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No. 09-

IN THE

Supreme Court of the United States

MEDELA AG and MEDELA, INC.,

Petitioners,

—against—

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

PETITION FOR A WRIT OF CERTIORARI

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August 13, 2009

QUESTION PRESENTED

To qualify for patent protection, a claimed invention must constitute "non-obvious subject matter." 35 U.S.C. § 103. This Court has long held that "[t]he ultimate judgment of obviousness is a legal determination." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007) (citing *Graham v. John Deere Co.*, 383 U.S. 1, 17 (1966)). Under Federal Circuit precedent, however, a person accused of patent infringement has no right to independent judicial, as distinct from lay jury, determination of obviousness. Rather, the Federal Circuit has held that a jury may render a verdict on the ultimate issue of obviousness, and that court review of such a verdict is limited to (i) "recreating" facts that "may have been found" by the jury in reaching its legal conclusion of obviousness, and then (ii) inquiring whether there was any permissible legal rationale that the jury might have adopted in reaching its legal conclusion of obviousness. Federal Circuit precedent on this point conflicts with two en banc decisions of regional circuit courts.

The question presented is:

Whether a person accused of patent infringement has a right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies the "non-obvious subject matter" condition for patentability.

RULE 29.6 STATEMENT

Pursuant to this Court's Rule 29.6, Petitioners identify Medela Holding AG and Olle Larsson Holding AG as parent corporations.

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Medela AG and Medela, Inc. hereby petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this action.

OPINIONS BELOW

The opinion of the Court of Appeals is reported at 554 F.3d 1010 and is reproduced in Appendix A. The jury verdicts relevant to this Petition are reproduced in Appendix B. The final judgment of the District Court is reproduced in Appendix C. The District Court's opinion denying Petitioners' renewed motion for judgment as a matter of law is unreported and is reproduced in Appendix D.

JURISDICTION

The final judgment of the Court of Appeals was entered on February 2, 2009. A petition for rehearing was timely filed on February 17, 2009, and was denied on March 31, 2009. By Order dated June 22, 2009, this Court extended Petitioners' time to file a petition for a writ of certiorari to and including August 13, 2009. This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

The district court had jurisdiction to hear this action under at least 28 U.S.C. § 1338(a). The Federal Circuit had jurisdiction to hear Respondents' appeal and Petitioners' cross-appeal under 28 U.S.C. § 1295(a)(1).

STATUTORY PROVISION INVOLVED

35 U.S.C. § 103(a) prescribes the "non-obvious subject matter" condition for patentability. The text of this section is reproduced in Appendix E.

STATEMENT OF THE CASE

One of the most important conditions for patent validity is the requirement set forth in 35 U.S.C. § 103(a) that a claimed invention must have been "non-obvious subject matter" at the time of its making by a patent applicant. *See* Robert P. Merges and John F. Duffy, *Patent Law and Policy* 611-12 (4th ed.

2007) (describing nonobviousness as "the ultimate condition of patentability" and "the final gatekeeper of the patent system") (internal quotations omitted). This case presents the question whether a person accused of patent infringement has a right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies that condition for patentability.

The "non-obvious subject matter" condition in § 103 was first codified by Congress in 1952 and first interpreted by this Court in the seminal case of *Graham v. John Deere Co.*, 383 U.S. 1 (1966). *Graham* held that "the ultimate question of patent validity is one of law," *id.* at 17, and was to be "determined" by reference to "several basic factual inquiries" including "the scope and content of the prior art," the "differences between the prior art and the claims at issue," and "the level of ordinary skill in the pertinent art." *Id.*

The *Graham* Court described its opinion as "focus[ing] attention on the *appropriate standard to be applied by the courts*," *id.* at 18 (emphasis added), and stated "that the inquiry which the Patent Office and *the courts must make as to patentability* must be beamed with greater intensity on the requirements of § 103." *Id.* at 19 (emphasis added). Furthermore, the Court described the *Graham* litigation in the lower courts as "present[ing] a *conflict between two Circuits* over the validity of a single patent." *Id.* at 4. These and other statements in the *Graham* opinion strongly suggested that judges, not juries, were required to undertake the complex weighing and balancing of factors that answered "the ultimate question of patent validity" as "one of law." *Id.* at 17.

In subsequent cases interpreting the nonobviousness requirement of § 103, this Court reiterated that the "ultimate test of patent validity is one of law," *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 280 (1976), and repeatedly engaged in independent assessments of whether subject matter claimed in a patent was properly deemed "non-obvious subject matter." *See,*

e.g., *Dann v. Johnston*, 425 U.S. 219, 230 (1976) ("The gap between the prior art and respondent's system is simply not so great as to render the system nonobvious to one reasonably skilled in the art"); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 62-63 (1969) ("We conclude further that to those skilled in the art the use of the old elements in combination was not an invention by the obvious-nonobvious standard."); *United States v. Adams*, 383 U.S. 39, 51 (1966) ("We conclude the Adams battery was also nonobvious."). In all of these cases the Court identified the relevant prior art and engaged in complex reasoning and analysis en route to reaching its judgment. In none of these cases did the Court suggest that juries, rather than judges, could properly determine whether an asserted patent claim satisfied the § 103 condition as a legal matter.

The extent to which judges, rather than juries, were required to determine obviousness under 35 U.S.C. § 103 was such an important issue that two regional circuit courts adjudicated the issue in en banc decisions before intermediate appellate jurisdiction in patent cases was centralized in the Federal Circuit in 1982. *See Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1341-44 (7th Cir. 1983) (en banc); *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647, 651 (9th Cir. 1982) (en banc) (per curiam). The Seventh and Ninth Circuits both held, en banc, that judges must independently determine whether proven facts lead to a legal conclusion of obviousness.

Starting in October 1982, appeals from judgments in civil actions "arising under" federal patent law were diverted from the regional circuits to a then newly-created intermediate appellate court, the Court of Appeals for the Federal Circuit. In sharp contrast with Seventh and Ninth Circuit precedent, the Federal Circuit took the position that lay juries can render verdicts that *preclude* independent judicial determination of the ultimate question of patent validity under § 103. Such jury verdicts typically take the form of simple "yes" or "no" answers to ques-

tions whether an asserted patent claim is invalid for obviousness.

Recognizing that a legal conclusion of obviousness or nonobviousness may rest on myriad different combinations of underlying historical facts and widely varying legal rationales, Federal Circuit precedent holds that post-trial or appellate review of a jury's verdict on the ultimate question of obviousness entails "*re-creating* the facts as they *may have been found* by the jury," and determining whether such hypothetical facts would be sufficient to support a legal conclusion of validity on *any* theory. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001) (emphasis added).

The present case well illustrates the operation of the Federal Circuit's approach and its practical effect, which is to eliminate any requirement that valid reasoning or analysis underlie a legal determination of obviousness or nonobviousness in patent litigation.

A. District Court Proceedings

In August 2003, Respondents sued Petitioners for alleged infringement of two patents that disclosed allegedly novel apparatus and methods for treating wounds by applying negative pressure to the wounded area. Respondents demanded trial by jury of all issues so triable. Petitioners denied infringement, pleaded affirmative defenses, and counterclaimed for a declaratory judgment that the asserted claims of Respondents' patents were invalid.

Following nearly three (3) years of pretrial proceedings, the case was called for jury trial. At the conclusion of the Respondents' evidence, Petitioners moved for judgment that the asserted claims were invalid under § 103 as a matter of law. The motion was denied. Petitioners then introduced evidence in support of their defense of invalidity and their counterclaim seeking a declaratory judgment of invalidity.

At the conclusion of all the evidence, the district court provided the jury with lengthy instructions that stated in part:

> In determining whether or not these claims would have been obvious, you should make the following determinations:
>
> First, what is the scope and content of the prior art?
>
> Second, what differences, if any, are there between the invention of the claims of the patents and the prior art?
>
> Third, what was the level of ordinary skill in the art at the time the invention was made?
>
> Fourth, are there any objective indications of non-obviousness?
>
> Against this background, you must decide whether or not the invention covered by the claims in this case would have been obvious.

The jury was further instructed that its "determinations" of the above-identified matters were in turn dependent on various subsidiary legal conclusions. With regard to "the scope and content of the prior art," the jury was instructed that (i) as to certain "documents and events, you will be required to determine whether such documents or events *qualify* as prior art"; (ii) "you should determine *what is disclosed* in the prior art"; and (iii) "[y]ou must decide whether this prior art *was reasonably relevant* to the particular problem the inventor faced in making the invention covered in the patent claims." (Emphasis added.)

With regard to "the level of ordinary skill in the art at the time the invention was made," the jury received instructions on (iv) the circumstances in which a claimed "invention" may be deemed to have been "made"; and (v) "[f]actors to consider in determining the level of ordinary skill in the art."

With regard to "objective indications of non-obviousness," the jury was instructed that "you must consider certain factors which, if established, *weigh* in favor of finding that the invention would not have been obvious." (Emphasis added.) The "factors" so identified included (vi) "whether the invention was commercially successful;" (vii) "whether the invention satisfied a long-felt need in the art;" and (viii) "whether the invention was copied by others in the art."

Finally, the district court propounded jury interrogatories that called for "yes" or "no" answers to the following questions:

> Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '643 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 17, please refer to pages 25-34 and 38-45 of the Court's Instructions.
>
> Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '081 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 18, please refer to pages 25-34 and 38-45 of the Court's Instructions."

The jury provided thirty-seven (37) "no" answers to the questions quoted above (one answer for each patent claim asserted). *See* Appendix B hereto.[1] The

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[1] The jury also found that Respondents had failed to prove infringement of the asserted patents; however, notwithstanding the finding of non-infringement, the

Footnote continued

jury was not asked to provide, and did not provide, any explanation of these "no" answers. It is quite literally impossible to determine what facts the jury considered to have been proved, or not proved, by Petitioners relevant to their counterclaim of invalidity under 35 U.S.C. § 103(a), or what process of reasoning led the jurors to reach their "no" answers.

Based on the jury's verdict, the district court issued a final judgment that Petitioners "take nothing on their counterclaims against the Plaintiffs for declarations of patent invalidity and patent unenforceability." *See* Appendix C hereto. The district court did not provide any reasoning or analysis in support of this judgment.

Petitioners then renewed their motion for judgment as a matter of law. Still, the district court declined to make any independent determination of the issue of obviousness. Applying Federal Circuit precedent, the district court stated (*see* Appendix D):

> Applying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict and thus declines to disturb it. The Court finds merit in Plaintiffs' credibility arguments. It is the province of the jury – not the judge – to determine the credibility of witnesses. In such a case as this, wherein highly qualified and devoted counsel represent both sides through a lengthy trial, jurors must wrestle with the credibility

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district court retained jurisdiction to determine the merits of the Petitioners' counterclaim for patent invalidity. *See Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 96-97 (1993).

> of lay and expert witnesses alike, whose juxtaposed opinions are often equally possible but entirely diametric. As such, while it may be true that Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors.

B. Federal Circuit Proceedings

Petitioners timely appealed to the Federal Circuit from the district court's judgment that they "take nothing" on their counterclaim against Respondents for a declaratory judgment of invalidity under 35 U.S.C. § 103(a). Petitioners argued that the district court erred by "fail[ing] to make its own legal determination of obviousness," by "treat[ing] the obviousness conclusion as a pure factual question," and by "merely h[o]ld[ing] that the jury could reasonably have relied on the testimony of KCI's expert and rejected Medela's expert." Pet. C.A. Br. at 54.

In reviewing the district court's judgment on this issue, the Federal Circuit stated that "[t]he scope and content of the prior art are factual questions to be determined by the jury," App. at 17a, but because the jury in this case made no findings on those matters, the Federal Circuit applied its highly deferential standard of review: "This court reviews these factual determinations, 'whether explicit *or implicit within the verdict*, for substantial evidence.'" *Id.* (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)) (emphasis added).

The phrase "implicit within the verdict" does not, in this context, connote factual findings that a jury must actually and necessarily have made, but rather refers to *hypothetical* factual "findings" that a jury *might* (or might not) have made. *See Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1304 (Fed. Cir. 2005) ("In re-creating the facts as they *may*

have been found by the jury, and in applying the *Graham* factors to the evidence of record in this case, we assess the evidence in the light most favorable to the verdict winner.") (quoting *McGinley*, 262 F.3d at 1351) (emphasis added).

Applying this standard, the panel majority cited disputed testimony that prior art references, including printed publications, purportedly "did not teach or suggest 'treating a wound with negative pressure,'" App. at 19a, and concluded: "we *must assume* that the jury found that the prior art does not disclose 'treating a wound with negative pressure' within the meaning of the patents." App. at 20a (emphasis added). Whether the jury *actually* made any such finding in this case, or utilized legal reasoning that was similar to that utilized by the panel below, is impossible to know or to determine.

For all of the time and money that went into developing and presenting proofs on the legal issue of patent validity in this case, no court has ever, to this day, made any independent determination of that issue.

REASONS FOR GRANTING THE PETITION

Federal Circuit precedent broadly and improperly abrogates any right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies the nonobviousness requirement of 35 U.S.C. § 103(a).

Federal Circuit precedent on this point –

• conflicts with two en banc decisions of other circuits, both of which were unanimous in rejecting the very sort of jury procedure that was used in this case and in many other cases. (*See* Part I, *infra*.)

• conflicts with, or is in deep tension with, this Court's precedents on obviousness, which have repeatedly described obviousness as "a legal determination," *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 427 (2007), stated that obviousness analysis was to be conducted by "a court, or patent examiner" (*id.* at

407), and instructed that "this analysis should be made explicit" so as "[t]o facilitate review" (*id.* at 418). (*See* Part II, *infra.*)

• is difficult or impossible to reconcile with settled principles of federal administrative law, under which the power to "pass on the validity of an administrative order" is reserved exclusively to courts, not juries, even in actions where a right to trial by jury exists and the invalidity of the administrative action is a legal defense to the action. *See Cox v. United States*, 332 U.S. 442, 453 (1947). (*See* Part III, *infra.*)

As shown by numerous objective indicators (discussed in Part IV, *infra*), the existence and extent of a litigant's right to independent judicial, as distinct from lay jury, determination of patent claim validity under 35 U.S.C. § 103 is a question of broad and general importance. Not only have two circuit courts thought the issue important enough to have it resolved through en banc decisions, but this Court previously granted certiorari on the closely related (though more narrow) issue of whether a patentee has a right to trial by jury in a civil action seeking a declaratory judgment of patent invalidity. *See Am. Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995). That case, however, was rendered moot after the respondent patentee dropped his jury demand, *see* 515 U.S. 1182 (1995), *vacating* 50 F.3d 966 (Fed. Cir.).

A federal study on reform of the patent system has identified excessive reliance on juries as "a serious threat to the patent system" and has singled out the use of juries in deciding validity issues as the area generating the greatest amount of public concern. The issue has also sparked a fierce and vigorous debate among commentators, many of whom have sharply criticized the use of juries for deciding patent validity issues.

Finally, the question presented here also fits squarely within the type of matters on which this

Court has seen fit to exercise its certiorari power in Federal Circuit patent cases.

I. THERE IS AN ACKNOWLEDGED CIRCUIT SPLIT.

In *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647 (9th Cir. 1982) (en banc), the court ruled that, because obviousness is a question of law, "[t]he court must, in all cases, determine obviousness as a question of law independent of the jury's conclusion." *Id.* at 651. The jury's role under *Sarkisian* is limited to, at most, (i) finding predicate facts through "detailed special interrogatories," *id.* at 650, and (ii) providing a "nonbinding advisory opinion" on obviousness that a court may use "for guidance." *Id.* at 651.

The Federal Circuit has repeatedly acknowledged that its precedent conflicts with the Ninth Circuit's en banc *Sarkisian* decision. In *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 895 n.5 (Fed. Cir. 1984), the Federal Circuit pointedly criticized *Sarkisian*, stating that "[t]he view suggested in *Sarkisian*, that a jury verdict on nonobviousness is at best advisory, would make charades of motions for directed verdict or JNOV under Fed.R.Civ.P. 50 in patent cases."

Perkin-Elmer rejected the Ninth Circuit's view that the courts must "determine nonobviousness 'independently' of the jury's verdict," *id.* at 895 (quoting *Sarkisian*), and instead held that, in reviewing a jury's verdict on the legal issue of obviousness, the "appropriate question" to be asked by a reviewing court is: "can the jury's *presumed findings* support [a] conclusion of nonobviousness encompassed in the jury's *verdict of validity*?" *Id.* (emphasis added).

The Federal Circuit's rejection of *Sarkisian* was again made clear in *Richardson* v. *Suzuki Motor Co.*, 868 F.2d 1226 (Fed. Cir. 1989). In that case, the district court for the Central District of California followed the Ninth Circuit's rule from *Sarkisian*: The district judge had used an "advisory" jury verdict on obviousness and had "independently decided" the va

lidity questions presented in the case, including obviousness. *Id.* at 1234. Though the jury and district judge were in agreement on the outcome, the Federal Circuit went out of its way to describe the *Sarkisian* procedure as "this discredited procedure of advisory verdicts," and specifically stated that "[i]t is established that the jury may decide the questions of anticipation and obviousness, either as separate special verdicts or en route to a verdict on the question of validity, which may also be decided by the jury." *Id.* To support that proposition, the court set forth a long string cite exclusively devoted to Federal Circuit precedents.

Petitioners in this case specifically argued to the Federal Circuit that "the district court erred by failing to conduct its own obviousness analysis." App. at 19a. In rejecting that argument, the Federal Circuit (consistently with its precedent) treated the jury's verdict on the ultimate question of obviousness as *precluding* independent judicial determination of the legal issue of obviousness, and as instead requiring a reviewing court to hypothesize "implicit" factual determinations (App. at 17a) and to "assume" that the jury adopted a permissible legal rationale. App. at 20a.

Not only is this procedure inconsistent with the Ninth Circuit's ruling in *Sarkisian*, but it purports to eliminate any requirement that valid reasoning or analysis underlie a legal determination of obviousness or nonobviousness. From the jury's "no" answers to questions whether "the Defendants [had] proven by clear and convincing evidence that the invention . . . [was] obvious" (*see* Appendix B), it is impossible to know what process of reasoning led to that legal conclusion or to review the correctness of that reasoning.

The jurors might have found facts sufficient to render the claimed inventions legally obvious but then erred in their analysis of obviousness (which is a difficult doctrinal area of patent law). Or the jury might have found nothing to be "clear" in a weeks-

long patent trial that concluded with pages of instructions on the legal tests of obviousness. But under the Federal Circuit rule applied below, a reviewing court is said to be required to "recreat[e] the facts as they *may have been found* by the jury," *Group One*, 407 F.3d at 1304 (quoting *McGinley*, 262 F.3d at 1351) (emphasis added), and then to apply a legal analysis that could be entirely different from whatever unstated and unknowable reasoning process might have underlain a jury's § 103 validity analysis.

This approach—treating a jury verdict on obviousness as requiring a court to hypothesize factual determinations and legal reasoning that may (or may not) have underlain the verdict—is also plainly inconsistent with the approach of the Seventh Circuit in *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324 (7th Cir. 1983) (en banc). There, as here, the district court had submitted the question of obviousness to a jury, and the jury had returned the answer, "We, the jury, find that the subject matter of the [patent in suit] was not obvious to one of ordinary skill in the art in the years 1963-64." *Id.* at 1328. The district court did not treat that jury verdict as merely advisory but instead, after "compos[ing] no findings of its own," issued judgment declaring that the patent was "good and valid in law." *Id.* at 1329 (quoting the district court's ruling).

The *Roberts* court condemned this procedure as "deficient in every respect" and ruled that "[t]he trial court abdicated its control over the legal issue [of obviousness]." *Id.* at 1342. Under the approach set forth in *Roberts*, jury verdicts can be given weight in obviousness analysis only if the jury has been asked to make findings on specific facts or if the trial judge has specifically instructed the jury that it must render a particular verdict "if it finds facts A, B, C, and D." *Id.* at 1341. On this point the *Roberts* en banc court was unanimous, for even Judge Posner (who dissented as to whether the particular patent was obvious) noted that "[a]ll of us agree that the ultimate question of obviousness is for the court, not

the jury, and that the jury's role is limited to deciding subsidiary fact questions, of the who-did-what-to-whom variety." *Id.* at 1347 (Posner, J., dissenting on other grounds).

The *Roberts* court also considered, and rejected, a split panel decision from the Fifth Circuit, *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763 (5th Cir.), *reh'g denied*, 616 F.2d 892, *cert. denied*, 449 U.S. 1022 (1980), that endorsed a jury verdict review procedure that was virtually identical to what the Federal Circuit applied in this case. In *Control Components*, the district court instructed the jurors on the law of obviousness and then submitted to them the question whether the invention "would have been obvious to one of ordinary skill in the [relevant] art." *Id.* at 766-67. The Fifth Circuit then assumed that the jury "made implicit findings on each underlying factual inquiry," *id.* at 768, and affirmed the verdict on the ground that the jury's verdict was "supported by substantial evidence." *Id.* at 769.

In a partial dissent, Judge Rubin argued that the majority's position on this point was "a step further into the Serbonian bog that threatens to engulf patent litigation." *Id.* at 774. He noted that if the jury verdict on the ultimate legal issue is deemed to include "implicit findings on non-obviousness, then the trial court cannot review either the verdict or the underlying findings unless the standard for judgment notwithstanding the verdict is used." *Id.* at 775 (quoting Gary M. Ropski, *Constitutional and Procedural Aspects of the Use of Juries in Patent Litigation*, 58 J. Pat. Off. Soc'y 609, 685 (1976)). The result would be "that validity will 'effectively become a question for the jury, not one of law for the judge.'" *Id.* (quoting Ropski, *supra*).

The split panel in *Control Components* generated a dissent from denial of *en banc* rehearing in which Judge Brown, joined by three other judges, explained:

> This case is of exceptional importance because the issues it presents arise in every jury trial of a patent case. Submitting the obviousness issue to the jury for a general verdict, in the manner our previous decisions permit, appears to me to be inconsistent with the precept that "the ultimate question of patent validity is one of law." *Graham v. John Deere Co.* . . .

616 F.2d 892, 892 (5th Cir. 1980) (quoting *Graham*, 383 U.S. at 17).

Subsequently, in a unanimous panel decision authored by Judge Brown, *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982), the Fifth Circuit described Judge Rubin's partial dissent in *Control Components* as "cogent and convincing" and ruled that, if the issue of obviousness were tried to a jury, the special interrogatories favored by Judge Rubin should generally be used to determine the factual predicates of obviousness. *Id.* at 1071-72. Trial judges who did not use such interrogatories, the court warned, would bear a "heavy burden of convincing the reviewing court that [they] did not abuse [their] discretion." *Id.* at 1072. The court noted that its agreement with Judge Rubin's position was motivated by the need to maintain "meaningful appellate review" over the legal issue of patent validity. *Id.*[2]

Thus, the issue presented in this petition engages a circuit split with at least two en banc regional cir-

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[2] Though the Seventh Circuit in *Roberts* expressly disagreed with the panel majority in *Control Components*, the court noted with approval that "Judge Rubin's viewpoint [in his partial dissent] has found favor in a subsequent Fifth Circuit decision." *Roberts*, 723 F.2d at 1342 n.24 (citing *Baumstimler*, 677 F.2d 1061).

cuits against the Federal Circuit's position. In addition, the Fifth Circuit either has an intra-circuit split or has moved into alignment with the circuits opposing the Federal Circuit position.

Although the Federal Circuit currently has exclusive intermediate appellate jurisdiction to hear appeals from final judgments in civil actions "arising under" federal patent law, *see* 28 U.S.C. § 1295(a)(1), this Court has continued to use circuit splits to identify which Federal Circuit patent cases merit a grant of certiorari. For example, in *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55 (1998), the petitioner argued, as one reason for granting certiorari, that the Federal Circuit had diverged from the approach taken by regional circuits prior to the creation of the Federal Circuit. *See* Petition for Writ of Certiorari, *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55 (1998) (No. 97-1130), 1998 WL 34081020, at *9-*10 & n.10. This Court granted certiorari and, in its opinion, specifically noted the circuit split as one factor justifying the court's grant of certiorari. *See Pfaff*, 525 U.S. at 60. Similarly, this Court granted certiorari in *KSR* where the petition for certiorari also relied on an acknowledged circuit split between Federal Circuit and regional circuit law. *See* Petition for Writ of Certiorari, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) (No. 04-1350), 2005 WL 835463, at *20-*21.

Furthermore, in his concurrence in *Holmes Group, Inc. v. Vornado Air Circulation Systems, Inc.*, 535 U.S. 826 (2002), Justice Stevens stated that circuit splits remain helpful to this Court in identifying patent cases warranting a grant of certiorari. *See id.* at 839 (noting that a "conflict in [circuit] decisions [on patent law issues] may be useful in identifying questions that merit this Court's attention"). Justice Stevens also noted that "decisions by courts with broader jurisdiction will provide an antidote to the risk that the specialized court may develop an institutional bias." *Id.* Circuit splits engaging en banc decisions of the regional circuits should be especially helpful to this Court in making certiorari decisions

because the decision to consider the issue *en banc* provides an additional indication of importance.

II. THE FEDERAL CIRCUIT'S APPROACH CONFLICTS WITH, OR IS IN DEEP TENSION WITH, THIS COURT'S PRECEDENTS ON OBVIOUSNESS.

Federal Circuit jury trial precedent is also difficult or impossible to reconcile with this Court's precedents on obviousness. For more than four decades, this Court has held that "the ultimate question of patent validity is one of law." *Graham*, 383 U.S. at 17. Moreover, in its recent *KSR* decision, this Court went beyond confirming, once again, that "[t]he ultimate judgment of obviousness is a legal determination," 550 U.S. at 427, but also stated multiple times that the obviousness analysis was to be conducted by courts or patent examiners, with no mention whatsoever of juries conducting the analysis. *See id.* at 407 ("If a court, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103."); *id.* at 420 & 421 (describing the analysis conducted by "courts and patent examiners" under the case law on obviousness).

The *KSR* Court also instructed that "[t]o facilitate review, this [obviousness] analysis should be made explicit." *Id.* at 418. Not even the most elaborate of special jury verdict forms under Federal Rule of Civil Procedure 49 can yield an "explicit" "analysis" of whether or why subject matter claimed in an issued patent should or should not be deemed "non-obvious subject matter" as a legal matter. Yet under the Federal Circuit-sanctioned procedure that was applied in this case, the entire "analysis" of obviousness can consist of a jury's "yes" or "no" answer to the legal question whether an asserted patent claim was "proven" to have encompassed "obvious" subject matter by "clear and convincing evidence." Such a black box verdict hides all analysis and substantially thwarts effective review, because no one can be sure what reasoning process led the jury to its ultimate

legal conclusion of obviousness. *See* Kimberly A. Moore, *Juries, Patent Cases, & a Lack of Transparency*, 39 Hous. L. Rev. 779, 791 (2002) ("the Federal Circuit presumes that all of the jury's reasoning was correct unless there are no facts in the record that would have supported that verdict").

Here the jury was given about seven (7) pages of instructions on the patent law of obviousness (at least one full page of which was devoted mainly to listing the pieces of prior art to be considered). While six or seven pages of complex instructions on the law of obviousness may certainly seem lengthy to jurors having no educational background in law, the instructions are themselves *nothing more* than a nutshell's nutshell of the law in this area. One leading casebook on patent law devotes over 160 pages to the exposition of obviousness law. *See* Merges & Duffy, at 611-780. Even a leading summary of the law—one marketed merely as an introductory aid for law students—spends over twenty-five pages on obviousness law. *See* Janice M. Mueller, *Introduction to Patent Law* 167-194 (2006); *see also id.* at backcover (noting that the work is designed to be an "accessible" aid for "law students"). Another popular student aid spends over forty pages on the area. *See* Martin J. Adelman et al., *Patent Law in a Nutshell* 144-88 (2008).

Even with such books, law students are not supposed to learn patent obviousness law without engaging in significant study and without also receiving hours of classroom instruction. By contrast, under the Federal Circuit's authorized procedure, lay jurors with no legal training whatsoever are supposed to learn patent obviousness law on the basis of less than ten pages of text and, at most, a few minutes of oral instruction by the trial judge. The jurors' subsequent "yes" or "no" answers to legal questions are then used to hypothesize "implicit" factual findings and legal reasoning that may never, in fact, have existed. The entire procedure seems to be a polar opposite from the explicit and careful process of

legal analysis that *KSR* and this Court's earlier precedents have mandated that courts should follow in analyzing the legal issue of obviousness.

III. THE FEDERAL CIRCUIT'S APPROACH IS DIFFICULT OR IMPOSSIBLE TO RECONCILE WITH SETTLED PRINCIPLES OF ADMINISTRATIVE LAW.

As this Court has previously recognized, "[a] patent, in the last analysis, simply represents a legal conclusion reached by the Patent Office." *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969). The Patent Office (now renamed the Patent and Trademark Office or "PTO") is an administrative agency that is generally subject to standard principles of administrative law. *See Dickinson v. Zurko*, 527 U.S. 150, 154 (1999). This Court has previously emphasized that, in light of "the importance of maintaining a uniform approach to judicial review of administrative action," the Federal Circuit must review the PTO under the same standards applied to other agencies. *Id.*

In other contexts involving court actions based on a predicate administrative action, litigants are permitted to raise the invalidity of the administrative action as a defense. This Court, however, has clearly stated that the validity of the agency's action is a matter for a court's independent judgment.

The leading case, *Cox v. United States*, 332 U.S. 442 (1947), involved a criminal prosecution for violating an administrative order authorized under the Selective Training and Service Act. The defendants in the case were Jehovah's Witnesses who had already been granted conscientious objector status. Conscientious objectors were, however, required by law to serve in civilian public service camps unless they could prove that they were "ministers," which would exempt them entirely from service. The defendants' claims to being ministers were rejected by local and appellate boards of the selective service system, and the defendants were ordered to report to public ser-

vice camps. The government criminally prosecuted the defendants after they either failed to go to camp or went to camp but then fled.

After deciding that the defendants could raise the invalidity of the administrative orders as a defense, this Court addressed whether the invalidity defense should be adjudicated by the judge or the jury. In his plurality opinion for four Justices, Justice Reed reasoned that "[t]he concept of a jury passing independently on an issue previously determined by an administrative body *or reviewing the action of an administrative body* is contrary to settled federal administrative practice." *Id.* at 453 (Reed, J.) (emphasis added). Justice Reed opined that "the constitutional right to jury trial does not include the right to have a jury pass on the validity of an administrative order." *Id.* On this point, Justice Reed's opinion appears to speak for the Court majority, for Justice Douglas's opinion (which was joined by Justice Black) expressly agreed with the four-Justice plurality opinion that the validity of the administrative order "is properly one of law for the Court" and "join[ed] in the opinion of the Court" on the issue. *Id.* at 455.

Nothing in *Cox* denies that judicial review of an administrative order may require some degree of factfinding. Indeed, Justice Reed specifically referred to the "analogous power of a judge as to admissibility," *id.* at 453 n.5, which of course includes the power to find facts necessary to rule on the point of law, *see id.* (citing precedents such as *Steele v. United States*, 267 U.S. 505, 510-511 (1925) and *Ford v. United States*, 273 U.S. 593, 605 (1927), which sustained the power of courts to find facts necessary to resolve admissibility disputes); *Gila Valley, Globe & N. Ry. Co. v. Hall*, 232 U.S. 94, 103 (1914) (holding that any "question of fact" necessary for an admissibility determination is "one to be determined by the trial court, and not by the jury").

Both of the leading commentators on administrative law from the mid-twentieth century recognized

Cox as standing for the general proposition that, in actions brought on the basis of an administrative order where the invalidity of the order is a proper defense, the court should "withhold[] from the jury the validity of the order." Kenneth Culp Davis, *Administrative Law Treatise* § 8.16, at 597 (West 1958); *see also id.* (noting that "seven Justices" agreed on this point in *Cox*). *See also* Louis L. Jaffe, *Judicial Control of Administrative Action* 394 (Little Brown 1965) (explaining *Cox* to mean that, even though the "validity of an administrative order depends on certain facts," those facts "need not be determined by a jury" because they go only to "the validity of the order," which is reserved for the court).

The case for jury participation is much weaker in the context of determining patent obviousness than it was in *Cox*. Not only did *Cox* involve a criminal prosecution, but the party seeking the jury trial right was trying to secure *greater* scrutiny of an administrative action. Here, by contrast, the party favoring the jury trial right (the patentee) is trying to sustain an administrative action. Because the jurors are instructed that they must presume that every allowed patent claim is valid and may reach a conclusion of invalidity only if "clear and convincing evidence" supports such a conclusion, giving preclusive effect to a jury's lay opinion on the legal issue of obviousness does not foster a firm check on governmental action by ordinary citizens but, to the contrary, tends to insulate PTO agency actions from effective judicial review.

Cox articulates a general norm applicable to judicial review of federal administrative action. The Federal Circuit's rule conflicts with that norm. In similar circumstances, this Court has previously granted certiorari in cases to review whether the Federal Circuit's patent jurisprudence has diverged from basic rules of law applicable in other areas.

For example, in *eBay Inc. v. MercExchange L.L.C.*, 547 U.S. 388 (2006), the Petition for Certiorari relied heavily on the divergence between the Fed-

eral Circuit's rules for granting an injunction in patent cases and the equitable rules governing injunctions in other areas of law. *See, e.g.*, Petition for Writ of Certiorari, *eBay v. MercExchange*, 547 U.S. 388 (2006) (No. 05-130), 2005 WL 1801263, at *13-*22. This Court granted certiorari, 546 U.S. 1029 (2005), and unanimously reversed on the ground that the injunction practice in patent cases must follow "the traditional four-factor framework that governs the award of injunctive relief" generally. 547 U.S. at 394.

Similarly, in *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007), the Petition for Certiorari argued that the Federal Circuit's standards for permitting a declaratory judgment action in patent disputes had diverged from the more general standards applicable to declaratory judgment actions in other areas of law. *See* Petition for Writ of Certiorari, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007) (No. 05-608), 2005 WL 3067195 at *8-*16. The Court granted certiorari and also reversed, relying on declaratory judgment precedents from non-patent cases to overturn the Federal Circuit's precedents on the availability of declaratory judgment jurisdiction in patent cases. *See* 549 U.S. at 126-33.

Thus, divergence between general legal principles and Federal Circuit patent law precedents has in the past provided a compelling reason to grant certiorari (and, ultimately, to reverse the Federal Circuit). In this case, the conflict between the general principle of administrative law articulated in *Cox* and the Federal Circuit rule is merely one of many reasons to grant certiorari.

IV. THE ISSUE IS IMPORTANT AND WORTHY OF THIS COURT'S ATTENTION.

Numerous objective indications demonstrate that the question presented by this Petition is an extremely important issue for the patent system.

1. *The Grant of Certiorari in Lockwood.* First, as discussed above, the issue has already provoked a

wealth of judicial opinions on the subject, including two en banc circuit court decisions, a dissent from denial of rehearing en banc in the Fifth Circuit, and a likely intra-circuit split in the Fifth Circuit. But perhaps the best gauge of importance is this Court's prior grant of certiorari in *American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995) (No. 94-1660).

The *Lockwood* litigation was similar to this case in many respects. After the plaintiff brought a patent infringement action, the defendant raised patent invalidity as a defense and counterclaimed for a declaratory judgment of patent invalidity (as the Petitioners here did). *See In re Lockwood*, 50 F.3d 966, 968-69 (Fed. Cir. 1995). In *Lockwood*, however, the defendant won a summary judgment of noninfringment. The issue then became whether the plaintiff-patentee had a jury trial right on the defendant's counterclaim for a declaratory judgment of patent invalidity. The district court granted a motion to strike the patentee's jury demand. On a petition for writ of mandamus, the Federal Circuit reversed and ordered the district court to hold a jury trial on the invalidity defense.

Dissenting from the denial of rehearing en banc, Judge Nies (joined by Judges Archer and Plager) argued that the "mandamus order in this case creates the type of conflict with other circuits that warrants Supreme Court review." *Id.* at 987 (Nies, J., dissenting). Judge Nies then detailed the circuit split discussed above, citing the en banc *Sarkisian* and *Roberts* decisions and the long line of contrary Federal Circuit precedents (*id.* at 987-90), and stated: "It is my understanding that the denomination of an issue as one of law represents a policy decision that a judge is more appropriate than a jury to make the decision. As a matter of policy for reasoned and uniform decisions, this is true of patent validity." *Id.* at 990.

After certiorari was granted in *Lockwood*, the patentee withdrew his jury demand and moved for dismissal of the Supreme Court case as moot. The-

reafter this Court vacated the grant of certiorari, 515 U.S. 1182 (1995). The prior grant of certiorari provides a strong indication that the allocation of decisional power between judge and jury on patent validity issues is important enough to warrant this Court's attention. Indeed, this Court granted certiorari in *Lockwood* (i) even though the Petition for Certiorari was interlocutory; (ii) even though the case involved the unusual procedural posture where the defendant had won summary judgment as to all the plaintiff-patentee's infringement claims and the counterclaim for a declaratory judgment of invalidity was all that was left to be tried; and (iii) even though the Supreme Court phase of the litigation was always susceptible to being rendered moot if the patentee withdrew his jury demand (which was in fact what ultimately happened).

The present case has none of those procedural oddities. The case arises from review of a final judgment; it involves the more typical situation where infringement and patent validity are tried together; and it is not susceptible to being rendered moot by the Respondent merely withdrawing a jury trial demand. Judge Nies was absolutely correct in 1995 that the conflict between Federal Circuit and regional circuit precedent "warrants Supreme Court review." *Lockwood*, 50 F.3d at 987.

2. *The 1992 Report to the Secretary of Commerce.* In 1992, a final report on patent law reform was issued by a special Advisory Commission convened by the Secretary of Commerce and consisting of leading representatives from U.S. businesses, universities, the patent bar, and the public at large. *See* The Advisory Commission on Patent Law Reform: *A Report to the Secretary of Commerce* (1992). Even by the time of this report, the Commission observed that "the proportion of jury trials has exploded to the point where between thirty and fifty percent of all patent trials employ a jury as the fact finder" and noted that this "dramatic increase in the use of juries is generating concern in the patent user community

that juries are being used to avoid the substantive merits of a patent dispute." *Id.* at 107. (While the 30-50% jury trial rate measured in 1992 did represent an alarming explosion compared to historical rates, the rate has since risen much higher. *See* point 3, *infra*.)

Many members of the Commission worried that "a serious threat to the patent system could be developing" as the public might come to believe the results of patent trials "are little more than a throw of the dice." *Id.* at 109. Already, the Commission found that, "[w]ithout exception," members of the public commenting on the subject "felt that the problems were serious, that jury trials were 'getting out of hand,' and that the use of jury trials should be curtailed if possible." *Id.* at 108. Moreover, the Commission specifically found that "[m]ost of the negative comments were focused on the use of a jury to determine patent validity." *Id.*

The Advisory Commission ultimately "hope[d] that by raising this issue, other bodies will initiate the appropriate studies and debate." The courts in general and this Court in particular, have long played a dominant role in allocating decisional power between judges and juries. As will be shown below, debate on jury trials has now continued for years, and thus it is now an appropriate time for this Court to enter the debate.

3. *Recognition of Importance in the Academic Literature.* The secondary literature has repeatedly recognized the importance of the issue presented here and has detailed the negative consequences flowing from the Federal Circuit doctrine.

For example, Professors Jaffe and Lerner have written: "a dramatic change that has occurred on the CAFC's watch is an increasing reliance on juries in patent trials." Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress* 123

(Princeton 2004). The statistics are presented in the table below:

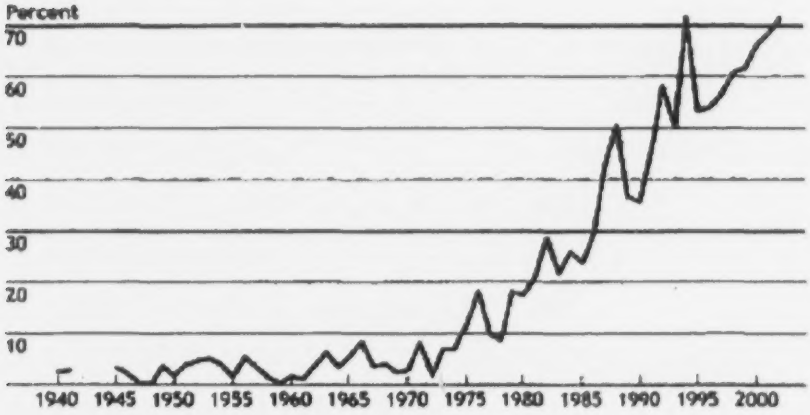

Figure 4.4 Share of patent cases tried before juries.

Jaffe and Lerner further note that, even though both judges and litigants have long been skeptical of the ability of juries to decide complex patent cases rationally, "the CAFC has taken a relatively sympathetic view of juries" and "has stated that patentees have an absolute right to a jury trial on questions of patent validity." *Id.* at 124. Jaffe and Lerner also show that the bias in favor of juries over judges produces a pronounced pro-patentee tilt to the law, as statistics demonstrate that "juries are more sympathetic to patentholders than judges." *Id.* at 125.

The reasons are readily discernable why a pro-jury bias is also pro-patentee: The Federal Circuit has forcefully instructed trial judges (i) that they must "clearly instruct[] jurors to presume the patent is valid," *id.*; (ii) that the presumption of validity cannot be overcome except by clear and convincing evidence; and (iii) that this "presumption is *never* annihilated, destroyed, or even weakened, regardless of what facts are of record." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.* 732 F.2d 1572, 1574-75 (Fed. Cir. 1984) (emphasis in original). Yet "the CAFC has

precluded the presentation to juries of information about the weaknesses and limitations of the patent examination process." Jaffe & Lerner, *supra*, at 124.

Thus, while judges familiar with administrative agencies in general and the PTO in particular might be more willing to take a more realistic view of the legal presumption of validity (as this Court did in *KSR*),[3] jurors may very well balk at second-guessing the action of an expert administrative agency, which comes to court clothed in a seemingly strong legal presumption of validity. Indeed, jurors may be quite rational to do so, for however faulty may be the judgment of the PTO, it might be better than that of jurors who are given seven pages of instructions and have no formal training on the patent law of obviousness. The solution to excessive juror deference to presumed administrative expertise is neither to give jurors more instructions on the foibles of administrative agencies nor to train them for a few weeks on the law of obviousness and patent validity. The solution is to recognize, as the Ninth Circuit did, that judges have the power and responsibility to review independently whether patents satisfy the statutory nonobviousness requirement.

As another commentator has recognized, the "increased use of juries and their expanded role in patent trials have clashed with a fundamental premise found in the legislation creating the Federal Circuit." Allan N. Littman, *The Jury's Role in Determining Key Issues in Patent Cases:* Markman, Hilton Davis *and Beyond*, 37 IDEA 207, 209 (1997). The legisla-

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[3] *See KSR*, 550 U.S. at 426 (invalidating a patent claim after noting "that the rationale underlying the presumption — that the PTO, in its expertise, has approved the claim — seems much diminished here" where the PTO had not considered the relevant prior art).

tion creating the Federal Circuit was generally thought to be needed to foster "nationwide uniformity in patent law" and to "make the rules applied in patent litigation more predictable." *Id.* at 210 (quoting legislative history of the legislation creating the court). Yet if "the application of basic doctrines of patent law are subsumed within jury verdicts, particularly general verdicts, uniformity, predictability and doctrinal stability could easily become hollow shells within which juries could do as they wished." *Id.*

The unpredictability introduced by jurors attempting to rule on legal issues such as obviousness is not good for the patent system. As Professor Jaffe has noted, "[h]aving decisions made by people who cannot really understand the evidence increases the uncertainty of the outcome. The combination of this uncertainty with the legal presumption of validity . . . is a big reason why accused infringers often settle rather than fight even when they think they are right." Adam B. Jaffe, *Patent Reform: No Time Like the Present*, 4 J. L. & Pol'y for Info. Soc'y 59, 72 (2008).

The secondary literature also shows that now is an excellent time to address the issue presented in this Petition. The persistence of the circuit split here makes it extremely unlikely that the lower courts will resolve the issue. Moreover, statements in this Court's recent *KSR* opinion have opened a vigorous debate about the continuing role of the jury in evaluating the nonobviousness of asserted patent claims. *Compare* Constantine L. Trela, Jr., *An Afterward to: A Panel Discussion on Obviousness in Patent Litigation:* KSR International v. Teleflex, 6 J. Marshall Rev. Intell. Prop. L. 633, 634 (2007) (asserting that the *KSR* decision suggests "that permitting the jury to decide the ultimate question of obviousness is wrong") *with* William F. Lee et al., *Reflections on the Ongoing Role of Juries in Determining Obviousness in Patent Cases After the Supreme Court's Decision in* KSR, 76 Patent, Trademark & Copyright

J. No. 1870, at 3 (BNA May 30, 2008) (arguing that "*KSR* would not seem to mandate any fundamental rethinking of the role of juries in determining obviousness").

Although the Federal Circuit now has jurisdiction over most patent appeals, this Court has frequently reviewed Federal Circuit patent decisions that "present an issue of the allocation of power among institutional actors." Mark D. Janis, *Patent Law in the Age of the Invisible Supreme Court*, 2001 U. Ill. L. Rev. 387, 409. *Cf. Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996) (holding that "the construction of a patent, including terms of art within its claim, is exclusively within the province of the court"). Such policing of institutional allocations of power is considered highly desirable even among those who otherwise advocate that this Court should "resist[] the temptation to speak directly on substantive doctrinal matters [of patent law]." Janis, *supra*, at 419.

Other commentators have also favorably remarked on this Court's apparent willingness to grant certiorari (i) to review "the allocation of decisional power within the patent system," John F. Duffy, *The* Festo *Decision and the Return of the Supreme Court to the Bar of Patents*, 2002 Sup. Ct. Rev. 273, 340; (ii) "to bring patent related jurisprudence into conformity with rules applicable in other areas," Hon. Timothy B. Dyk, *Forward: Does the Supreme Court Still Matter?*, 57 Am. U. L. Rev 763, 769 (2008); or more generally (iii) "to prevent patent law from ossification and to ensure that appropriate policy considerations play a role in the development of the law." *Id.* at 763. *See also* John M. Golden, *The Supreme Court as "Prime Percolator": A Prescription for Appellate Review of Questions in Patent Law*, 56 UCLA L. Rev. 657, 720 (2009) (arguing that Supreme Court review of patent cases is desirable "in areas where Federal Circuit decisions may have unduly ossified the law").

This case presents all of these factors: It is a case about the allocation of decisional power; the Federal

Circuit's rule deviates from standard principles of administrative law; and the Federal Circuit's exclusive jurisdiction has led to an ossified rule that had previously been the subject of intensive en banc scrutiny by the regional circuit courts.

The question presented by this Petition has generated a pitched and vigorous debate that is now fully joined. It is ripe for a decision by this Court.

CONCLUSION

For the reasons set forth above, this Petition for a Writ of Certiorari should be granted.

Respectfully submitted,

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APPENDIX

APPENDIX A — OPINION OF THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT DECIDED FEBRUARY 2, 2009

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

Appendix A

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

DECIDED: February 2, 2009

Before BRYSON, DYK, and PROST, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* PROST. Dissenting opinion filed by *Circuit Judge* DYK.

PROST, *Circuit Judge.*

Defendants Medela, Inc. and Blue Sky Medical Group, Inc. appeal the denial of their motion for judgment as a matter of law on obviousness and their alternative motion for a new trial on obviousness. They also appeal the district court's claim construction and failure to declare several claim terms indefinite. Plaintiff Kinetic Concepts, Inc. cross-appeals the denial of its motion for judgment as a matter of law on infringement and its alternative motion for a new trial on infringement.

For the reasons set forth below, we affirm.

I. BACKGROUND

Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences (collectively, "KCI") brought suit against Medela AG, Medela, Inc., Richard Weston, and Blue Sky Medical Group, Inc. (collectively, "Defendants"), alleging infringement of U.S. Patent Nos. 5,636,643 ("'643

patent") and 5,645,081 ("'081 patent"), as well as claims of false advertising, unfair competition, and conspiracy. Defendants responded with counterclaims alleging that the asserted patents were invalid and unenforceable. After a six week trial in the United States District Court for the Western District of Texas, the jury returned a verdict that the asserted patents were not shown to be invalid, unenforceable, or infringed. The jury also found against KCI on its false advertising, unfair competition, and conspiracy claims.

After trial, Defendants filed a motion for judgment as a matter of law ("JMOL") that the asserted claims are invalid as obvious under 35 U.S.C. § 103. In the alternative, Defendants requested a new trial on obviousness. KCI filed its own motion for judgment as a matter of law on infringement, or in the alternative, requested a new trial on infringement. The district court denied each of these motions.

Defendants now appeal the district court's denial of their JMOL motion on obviousness, arguing that under a proper claim construction no reasonable juror could have found that the prior art did not render the asserted patents invalid. In the alternative, Defendants ask us to order a new trial on obviousness because the Supreme Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), effected a supervening change in the law that retroactively rendered the jury instructions on obviousness erroneous. They also appeal the district court's determination that "selected stage of healing," "reduction in bacterial density in the wound

by at least 50%," and "screen for prevention of overgrowth" are not indefinite claim limitations. KCI cross-appeals alleging that the district court erred by denying its motion for JMOL of infringement, and alternatively, requests a new trial on infringement because Defendants presented a "practicing the prior art" defense, compared the accused product to KCI's product, and engaged in "class warfare" before the jury.

We have jurisdiction under 28 U.S.C. § 1295(a)(1).

A. The Asserted Patents

The patents at issue relate to treating difficult-to-heal wounds by applying suction, which is referred to in the patents as "reduced pressure" or "negative pressure." Claims 1 and 11 of the '643 patent, with emphases added, are illustrative:

> 1. An appliance for administering a *reduced pressure treatment to a would* [sic] comprising:
>
> (a) an impermeable cover adapted to cover and enclose the wound and adapted to maintain reduced pressure at the site of the wound;
>
> (b) a seal adapted to seal said cover to tissue surrounding the wound;

Appendix A

(c) reduced pressure supply means for connection to a source of suction, said reduced pressure supply means cooperating with said cover to supply said reduced pressure beneath said cover; and

(d) a *screen adapted to prevent overgrowth* of wound tissue, said screen being located between said wound and said cover.

11. A method *treating a wound* comprising the steps of:

(a) applying a reduced pressure to the wound, wherein said applying step comprises the steps of:

(i) placing a porous *screen* over the wound;

(ii) locating an impermeable cover over the wound, said cover having a suction port;

(iii) sealing the periphery of said impermeable cover to tissue surrounding the wound; and

(iv) operably connecting said suction port with a vacuum system for producing said reduced pressure; and

(b) maintaining said reduced pressure until the wound has progressed toward a *selected stage of healing.*

In addition to claims 1 and 11, KCI asserted claims 2, 3, 6, 7, 8, 12, 13, 14, 16, 26, 27, 28, 29, and 32 of the '643 patent. KCI also asserted claims 1, 3, 5, 8, 9, 11, 12, 13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, 64, 65, and 66 of the '081 patent.

The issues on appeal focus on six limitations, at least one of which is present in each of the asserted claims. First, each of the asserted claims in both the '081 and '643 patents requires using "reduced" or "negative" pressure to "treat a wound" or "facilitate the healing of a wound," either as part of the preamble[1] or the body of

1. The parties concede that the preambles are limiting with respect to this limitation.

the claim. Second, there is a "screen" or "screen means" limitation in each asserted claim of the '081 patent and claims 1, 2, 3, 11, and 12 of the '643 patent. Third, claims 12, 27, 33, 36, 37, 65, and 66 of the '081 patent and claims 13, 14, 28, and 29 of the '643 patent have limitations requiring the use of intermittent suction. Fourth, an "impermeable cover" limitation is present in claims 1, 2, 3, 6, 7, 8, 11, 12, 16, 26, 27, and 28 of the '643 patent.[2] Fifth, claims 11, 12, 29, and 32 of the '643 patent contain a limitation requiring treating toward a "selected stage of healing." Finally, claim 32 of the '643 patent recites "a reduction in bacterial density in the wound by at least 50%."

B. Claim Construction

The parties have devoted significant attention to the construction of "treating a wound" and "facilitating the healing of wounds." Defendants argued before the first claim construction order that "treating a wound," as used in claim 13 of the '643 patent, should be construed as "giving medical care to an injury," or in the alternative, "giving medical care to (1) trauma to any of the tissues in the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical

2. Defendants argue that impermeable covers were well known by persons of ordinary skill in the art. However, as discussed below, KCI presented substantial evidence that the prior art did not teach or suggest the "treating a wound with negative pressure" limitation, which was present in each of the asserted claims. Therefore, it is unnecessary for us to address the "impermeable cover" limitation.

incision." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("*Order Construing Patent '643 Terms*") (alteration in original). In response, KCI argued that "treating a wound" should be construed to mean "treating tissue damage to the surface of the body, including the epithelial and subcutaneous layers," or in the alternative, should not be construed because the jury would have no difficulty understanding the phrase's ordinary meaning. *Id.* at 5-6; Pl.'s Br. on Claim Construction 8-10, *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D.Tex. Mar. 7, 2005). In its first claim construction order, the district court construed the term "according to its plain and ordinary meaning as 'giving medical care to an injury.'" *Order Construing Patent '643 Terms* at 7.

After a *Markman* hearing on November 14, 2005, the district court issued a second claim construction order construing terms from the '643 and '081 patents. *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D.Tex. Jan. 24, 2006) ("*Order Construing Patents '643 and '081 Claim Terms*"). In this order, the court relied on its previous construction of "wound" as "injury" and construed "facilitating the healing of wounds" to mean "facilitating the healing of injuries." *Id.* at 9.

In the middle of the trial, however, the district court suggested vacating the construction of "wound" in light of the fact that the parties had yet to use the word "injury" in front of the jury. After clarifying on the

record that neither party was waiving its right to appeal, the court issued an order vacating its construction of "wound." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("*Second Amended Order Construing Patent '643 and '081 Claim Terms*"). As a result, "treating a wound" was construed to mean "giving medical care to a wound." *Id.* At trial, the jury was given this construction of "treating a wound," but was not instructed on the meaning of "facilitating the healing of wounds."

The construction of the "screen" limitation is also relevant to this appeal. The district court construed this term to mean "a porous material that applies a counteracting force to granulation tissue to stop growth of granulation tissue above the level of skin surrounding the wound, the porous material being positioned at the wound within the sealing means." *Order Construing Patents '643 and '081 Claim Terms* at 16-17.

C. The Prior Art

At trial, Defendants presented several prior art references that are relevant to this appeal. These include the Chariker-Jeter publications, the Chariker-Jeter prior uses, the Svedman article, the Johnson article, and the Davydov publications. KCI distinguished each of these references by arguing to the jury that they did not teach "treating a wound with negative pressure" and thus could not render the claimed invention obvious.

Appendix A

The Chariker-Jeter prior art presented at trial included a journal article, a book chapter, testimony from Dr. Chariker about public uses of the Chariker-Jeter system, and assorted presentation materials. The Chariker-Jeter system, as described by these references, was originally developed to treat certain wounds that were complicated by a hole in one of the patient's organs. Such a hole is commonly referred to as a "fistula." In broad terms, the system consists of lining the wound bed with gauze, placing one end of a tube in the wound, sealing a cover over the wound, and applying suction to the other end of the tube. Of the various Chariker-Jeter references, only one prior use, as described by Dr. Chariker in his testimony about the treatment of a patient, specifically disclosed using the Chariker-Jeter system on a wound that did not involve a fistula.

The second piece of prior art relied on by Defendants at trial was the Svedman article. This article describes placing a dressing over a wound, connecting a solution to a tube at one end of the dressing, and applying suction to a tube at the other end of the dressing. The effect is that the solution flows through the dressing and across the surface of the wound.

Defendants' third piece of prior art was the Johnson article, which describes anchoring a skin graft in place, cutting several "pie crust incisions" in the graft, covering the graft with gauze, inserting a suction drain, covering the entire area with a dressing, and applying suction.

The fourth and final piece of prior art was the Davydov reference, which consists of two articles that describe a treatment for infection in the mammary glands of nursing women. The treatment method consists of making an incision in the breast, placing a glass cup over the incision, and applying suction to drain the pus and bacteria.

II. DISCUSSION

Defendants appeal the district court's denial of their motion for JMOL of obviousness, or in the alternative, their request for a new trial on obviousness. Defendants also appeal the district court's construction of "wound" and its failure to find several claim terms indefinite. KCI cross-appeals the district court's denial of its motion for JMOL of infringement, or, in the alternative, its request for a new trial on infringement. We address each issue in turn.

A. Defendants' Motion for JMOL of Obviousness

The denial of a motion for JMOL is reviewed "under the law of the regional circuit where the appeal from the district court normally would lie." *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1346 (Fed. Cir. 2007) (quotations omitted). In the Fifth Circuit, JMOL "is appropriate only when a 'reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue.'" *Cambridge Toxicology Group, Inc. v. Exnicios*, 495 F.3d 169, 179 (5th Cir. 2007) (quoting Fed. R. Civ. P. 50(a)(1)). "We must affirm unless there is

no legally sufficient evidentiary basis for the jury's verdict." *Lane v. R.A. Sims, Jr., Inc.*, 241 F.3d 439, 445 (5th Cir. 2001) (internal quotations omitted).

Defendants allege several errors in the district court's treatment of its obviousness contentions. First, Defendants argue that the court's failure to construe "wound" prevented the jury from properly assessing whether the prior art was within the scope of the asserted claims. Second, Defendants argue that the district court erred by finding that substantial evidence supported the jury's finding that the patents were not obvious. Finally, Defendants contend that the district court was required to conduct its own independent obviousness analysis and erred by simply reviewing the jury's verdict for substantial evidence. We address each argument in turn.

1. Construction of "Wound"

Defendants argue that the district court erred by vacating its construction of "wound" when the term's meaning was critical to the obviousness inquiry. According to Defendants, this error allowed KCI to improperly avoid the prior art by arguing claim construction to the jury. Specifically, Defendants take issue with KCI's characterization at trial of the Chariker-Jeter, Svedman, Johnson, and Davydov references as "draining fistulae," "irrigating wounds," "immobilizing skin grafts," and "draining bodily fluids," respectively, as opposed to "treating wounds with negative pressure." Defendants' expert testified that

under the plain and ordinary meaning of "wound," each of the prior art references disclosed "treating a wound with negative pressure." The effect of this, according to Defendants, was that the jury was improperly forced to choose between competing claim constructions offered by the experts.

Defendants ask us to adopt their proposed "plain and ordinary meaning" construction, taken from Stedman's Medical Dictionary: "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision." They argue that the specification's use of broad language when describing the wounds that can be treated shows that the ordinary meaning, as defined in the dictionary, was intended. *See* '643 patent col.12 ll.41-42 ("Negative pressure appliances are useful for treating a variety of wounds."); *id.* col.13 ll.24-25 ("The present invention also includes a method of treating damaged tissue. . . ."). Additionally, Defendants cite the numerous examples in the '643 patent's specification that describe open wounds, infected wounds, burn wounds, skin graft and skin flap wounds, decubitus ulcer wounds, incisional wounds, chronic open wounds secondary to stasis ulcers, and wounds which respond to increased blood flow, to support their proposed construction.

KCI responds that any error resulting from the district court's failure to construe the "wound" phrases is harmless because Defendants' proposed construction is incorrect as a matter of law and the jury's verdict

demonstrates that it adopted the correct construction. According to KCI, the correct construction of "wound" is "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." KCI argues that while the specification may refer to a "variety of wounds," each and every example specifically described is a skin wound. Therefore, KCI alleges, the Stedman's Medical Dictionary definition is broader than the scope of the specification and cannot be used to define "wound" as used in the claims. Further, KCI notes that under Defendants' proposed construction, "wound" would include, in addition to fistulae, "conditions such as ruptured appendices and stomach ulcers" that the specification in no way suggests can be treated according to the claimed invention. Appellee's Br. 53.

As a threshold matter, it appears that the parties' dispute over the construction of "wound" only affects the Chariker-Jeter and Davydov references. At trial, KCI did not contest that "wounds" were the subject of both the Svedman and Johnson articles. For example, KCI's expert, Dr. Orgill, testified that, in the Johnson reference, "[t]he skin graft is closing the wound." J.A. 204,899. Similarly, Dr. Orgill described the Svedman article as teaching "irrigation of a wound." J.A. 204,923. Therefore, the effect of any error in the failure to construe "wound" is limited to the Chariker-Jeter and Davydov references.[3]

3. Defendants also argue that KCI improperly distinguished the prior art on the ground that it did not "treat" wounds. However, Defendants have not alleged error in the (Cont'd)

We agree with KCI that "wound," as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications and the "pus pockets" described in the Davydov references. As this court held in *Phillips v. AWH Corp.*, "the specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" 415 F.3d 1303, 1315 (Fed. Cir. 2005) (en banc) (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)). All of the examples described in the specification involve skin wounds. *See id.* at 1321 ("Properly viewed, the 'ordinary meaning' of a claim term is its meaning to the ordinary artisan after reading the entire patent."). To construe "wound" to include fistulae and "pus pockets" would thus expand the scope of the claims far beyond anything described in the specification. *See Nystrom v. TREX Co.*, 424 F.3d 1136, 1145 (Fed. Cir. 2005) ("[I]n the absence of something in the written description and/or prosecution history to provide explicit or implicit notice to the public—i.e., those of ordinary skill in the art-that the inventor intended a disputed term to cover more than the ordinary and customary meaning revealed by the context of the intrinsic record, it is improper to read the term to encompass a broader definition simply

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(Cont'd)

district court's construction of "treating" as "giving medical care to," nor have they asked us for a construction of "facilitating the healing of." *See Second Amended Order Construing Patent '643 and '081 Claim Term* at 2. Therefore, we confine our inquiry to the construction of "wound."

because it may be found in a dictionary, treatise, or other extrinsic source.").

We further conclude that the district court's failure to instruct the jury on the construction of "wound" in this case was harmless.[4] *See B. Braun Med., Inc. v. Abbott Labs.*, 124 F.3d 1419, 1423 (Fed. Cir. 1997) (holding that the district court's pre-*Markman* failure to instruct the jury on the construction of a means-plus-function limitation was harmless because the jury adopted the correct construction). Because the jury's verdict is supported under the proper construction, and because we perceive no danger under the circumstances of this case that the jury may have used an incorrect construction of "wound" that might have prejudiced Defendants, there is no need to remand for a new trial.

2. Substantial Evidence of Nonobviousness

Defendants next argue that regardless of which claim construction is used, the prior art references disclose "treating wounds with negative pressure."

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4. While *O2 Micro International, Ltd. v. Beyond Innovation Technology Co.*, 521 F.3d 1351 (Fed. Cir. 2008), permits a remand for further claim construction, it does not require one. Remanding is particularly unnecessary in this case, where claim construction was briefed before the district court and the disputed term was initially construed but later vacated because the parties did not use the construction in front of the jury. *See id.* at 1363 (remanding because "the district court is in the best position to determine the proper construction of this claim term in the first instance").

In support of this, Defendants cite the Chariker-Jeter publications that describe treatment of wounds complicated by fistulae, Dr. Chariker's testimony about the use of that method on a wound that did not include a fistula, the Svedman article, the Johnson article, and the Davydov articles.

The scope and content of the prior art are factual questions to be determined by the jury. *Graham v. John Deere Co. of Kan. City*, 383 U.S. 1, 17 (1966). This court reviews these factual determinations, "whether explicit or implicit within the verdict, for substantial evidence." *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001).

Defendants primarily rely on the Chariker-Jeter references, including the publications and Dr. Chariker's testimony at trial. However, KCI distinguished these references in front of the jury and presented substantial evidence that these references did not disclose "treating wounds with negative pressure." For example, Dr. Argenta, a witness for KCI and one of the named inventors on the asserted patents, testified that the Chariker-Jeter system is "totally different" from the claimed invention. Specifically, Dr. Argenta stated that the Chariker-Jeter method was designed for draining the effluent from fistulae, not treating a wound in order to increase granulation. Additionally, KCI's expert, Dr. Orgill, testified that the Chariker-Jeter references "deal[ ] with draining fistulas only, no[t] healing of the wound." With respect to Dr. Chariker's testimony about the use of the method on a patient whose wound did not

include a fistula, KCI purports to have impeached Dr. Chariker's testimony about this patient with contradictory deposition testimony. The jury was correctly instructed, however, that it was the "sole judge[ ] of credibility" and that it must decide which witnesses to believe. Moreover, Fifth Circuit law dictates that "in case[s] of conflicting expert testimony, the jury is entitled to make credibility determinations and believe the witness it considers more trustworthy." *Streber v. Hunter*, 221 F.3d 701, 726 (5th Cir. 2000) (quotations omitted). Based on our review of the record, we find that the testimony of KCI's witnesses was sufficient to allow the jury to reach the conclusion that the Chariker-Jeter method was not used to "treat a wound with negative pressure" as required by the claims.

We reach the same conclusion regarding the Svedman, Johnson, and Davydov articles. Dr. Orgill distinguished the Svedman technique on two grounds. First, Dr. Orgill told the jury that Svedman taught an irrigation device, not a device for treating a wound with negative pressure. Second, Dr. Orgill explained that the Svedman technique could not maintain negative pressure on the wound because the Vaseline between the dressing and the wound would become viscous when warmed by contact with human skin. With respect to the Johnson article, Dr. Orgill told the jury that the skin graft, not the negative pressure, was treating the wound. According to Dr. Orgill, the Johnson article simply described one of many ways to immobilize a skin graft to a wound. Finally, Dr. Orgill testified that Davydov did not teach treatment of a "wound" with

negative pressure. Rather, Dr. Orgill explained, the Davydov method was used to treat a "pocket of pus" that was "enclosed within the breast." According to Dr. Orgill, the only wound disclosed in the Davydov articles was the incision made to gain access to the "pocket of pus," which did not begin to heal until the suction device was removed.

Thus, KCI addressed each of Defendants' prior art references and provided the jury with a basis for determining that they did not teach or suggest "treating a wound with negative pressure," a limitation found in every asserted claim. We conclude that this was sufficient to support the jury's verdict of nonobviousness.[5]

3. The District Court's Review of the Jury's Verdict on Obviousness

Defendants' final argument with respect to its JMOL motion is that the district court erred by failing to conduct its own obviousness analysis. Defendants do not argue that submitting the question of obviousness to the jury is error. However, they assert that the district court strayed by "treat[ing] the obviousness conclusion as a pure factual question" and simply reviewing the jury's verdict for substantial evidence.

5. While this appeal was pending, claim 13 of the '643 patent was rejected during reexamination as obvious in view of two other Svedman references that were not relied on by Defendants in this appeal. Because those references were not argued before us, the results of the reexamination have no effect on this appeal.

Appellant's Br. 54. Because of this, Defendants argue, the district court never considered which *Graham* factors justified a nonobviousness verdict. Defendants allege that had such an analysis occurred, the district court would have concluded that the asserted patents were obvious.

Defendants' obviousness argument at trial relied heavily on the prior art references, the scope and content of which are factual questions to be determined by the jury. *See Graham*, 383 U.S. at 17. As discussed above, KCI presented substantial evidence to support its interpretation of the references. Thus, we must assume that the jury found that the prior art does not disclose "treating a wound with negative pressure" within the meaning of the patents. *See Arsement v. Spinnaker Exploration Co.*, 400 F.3d 238, 249 (5th Cir. 2005) (on appeal of a motion for JMOL, "the evidence, as well as all reasonable inferences from it, are viewed in the light most favorable to the verdict" (quotations omitted)). In light of this, we conclude that Defendants failed to establish that the asserted claims were obvious as a matter of law.

B. Defendants' Request for a New Trial on Obviousness

In the alternative to their request for JMOL of obviousness, Defendants seek a new trial on obviousness because of alleged errors in the jury instructions. At trial, the jury was instructed that:

> In order to prove obviousness, [Defendants] *must* prove by clear and convincing evidence that one of ordinary skill in the art at the time would have found in the prior art some teaching, suggestion or incentive to combine the prior art in the way [KCI] did in its invention.

J.A. 235 (emphasis added). Defendants concede that they stipulated to this instruction, but argue that a supervening change in the law resulting from *KSR* justifies their raising this issue for the first time on appeal. KCI responds that because Defendants stipulated to the instruction, any error was "invited" and is thus unreviewable. For the purpose of this review, we assume arguendo that Defendants did not invite the alleged error in the jury instructions.

Challenges to jury instructions are reviewed "under the law of the regional circuit where the district court sits." *Voda v. Cordis Corp.*, 536 F.3d 1311, 1328 (Fed. Cir. 2008). In the Fifth Circuit, an objection to the jury instructions first raised on appeal must "meet the exacting requirements of plain error." *Tompkins v. Cyr*, 202 F.3d 770, 784 (5th Cir. 2000). "To overturn a verdict for plain error in the instructions, we must find an obviously incorrect statement of law that was probably responsible for an incorrect verdict, leading to substantial injustice." *Id.* (citations and quotations omitted).

As discussed above, substantial evidence supports a finding that the Chariker-Jeter, Svedman, Johnson, and Davydov prior art references do not "treat wounds with negative pressure" as claimed in the asserted patents. The alleged error in the jury instruction relates to the "teaching, suggestion, or incentive to combine the prior art." Based on our conclusion that there was substantial evidence that *none* of the prior art references "treat wounds with negative pressure," we are not persuaded that the instruction on obviousness was "probably responsible for an incorrect verdict." *See id.*; *see also z4 Techs.*, 507 F.3d at 1355 (affirming denial of a new trial on obviousness after *KSR* because defendants failed to identify evidence establishing a prima facie case of obviousness). Accordingly, we affirm the district court's denial of Defendants' request for a new trial.

C. Defendants' Indefiniteness Arguments

The definiteness analysis requires a determination of "whether one skilled in the art would understand the bounds of the claim when read in light of the specification." *Personalized Media Commc'ns, LLC v. Int'l Trade Comm'n*, 161 F.3d 696, 705 (Fed. Cir. 1998) (quoting *Miles Labs., Inc. v. Shandon, Inc.*, 997 F.2d 870, 875 (Fed. Cir. 1993)). "If the meaning of the claim is discernible, even though the task may be formidable and the conclusion may be one over which reasonable persons will disagree, we have held the claim sufficiently clear to avoid invalidity on indefiniteness grounds." *Exxon Res. & Eng'g Co. v. United States*, 265 F.3d 1371,

1375 (Fed. Cir. 2001). Definiteness is a question of law, which we review de novo. *Id.* at 1376.

Defendants first argue that "selected stage of healing" is indefinite because the specification does not explain how the selected stage is to be determined for particular wounds at particular times. Further, Defendants argue that whether a wound has progressed to a selected stage of healing is wholly subjective. However, KCI points out that the specification of the '643 patent provides several examples of selected stages of healing. '643 patent col.12 ll.47-54. Additionally, KCI submitted a declaration from one of the named inventors of the asserted patents explaining that a doctor of ordinary skill in the art would understand how the selected stage of healing may vary from wound to wound. While it may be true that the patentee's ability to "articulate a definition supported by the specification . . . does not end the inquiry," Defendants have not shown in this case that a person of skill in the art would be unable to ascertain the meaning of the term. *See Halliburton Energy Servs. v. M-I LLC*, 514 F.3d 1244, 1251 (Fed. Cir. 2008). Accordingly, we conclude that "selected stage of healing" is not "insolubly ambiguous." *See Exxon*, 265 F.3d at 1375.

Relying on *Honeywell International, Inc. v. International Trade Commission*, 341 F.3d 1332, 1339-40 (Fed. Cir. 2003), Defendants also argue that "reduction in bacterial density in the wound by at least 50%" is indefinite because there are several methods for measuring bacterial density, each of which may yield

a drastically different result, and a person of ordinary skill in the art would not know which method to use. However, KCI responds that a person of ordinary skill in the art would know which method to use because Example 2 of the '643 patent describes a particular method. '643 patent col.15 ll.58-65. We agree with KCI that *Honeywell* does not control where, as here, several methods for calculating reduction in bacterial density are available but the specification discloses one particular method. Thus, we conclude that "reduction in bacterial density in the wound by at least 50%" is not indefinite.

Finally, Defendants argue that the claims reciting a "screen" are indefinite because a person of skill in the art would not know what "overgrowth of tissue in the wound" is or how a "screen" could prevent it. Defendants point to several parts of the record that allegedly present conflicting definitions of "preventing overgrowth," such as "preventing loculation," "removing bacteria," "removing dead tissue that sticks to the screen," and "preventing the formation of scar tissue." KCI argues in response that one of the named inventors defined overgrowth as "[g]rowth of granulation tissue above the surrounding uninjured tissue" and explained that the screen prevented this by "distribut[ing] the pressure" within the wound. KCI also asserts that the allegedly conflicting definitions are not definitions of "overgrowth" at all. Instead, KCI argues, Defendants are pulling quotes from the inventors' deposition testimony about various complications of wound healing and attempting to mischaracterize them

as definitions of "overgrowth." In light of KCI's explanation of the record before us, we are not persuaded that this claim term is "insolubly ambiguous." *See Exxon*, 265 F.3d at 1375. Accordingly, we find no error in the district court's failure to find the term indefinite.

D. KCI's Motion for JMOL of Infringement

We turn now to KCI's cross appeal on infringement. While several infringement theories were presented at trial, KCI limits its cross appeal to Blue Sky Medical Group, Inc.'s ("Blue Sky") alleged direct and induced infringement resulting from its sale of Versatile kits. Blue Sky assembles and sells several Versatile kits, each of which includes a Versatile pump and a combination of various "convenience items." The most basic kits include a Versatile pump, tubing, and a drain. Other kits include items such as Aquaphor gauze, adhesive dressing, scissors, and gloves. KCI alleges that Blue Sky's sale of certain kits directly infringed the asserted apparatus claims of the '081 patent and induced infringement of both the '081 claims and several method claims of the '643 patent. The jury rejected these contentions and the district court denied KCI's motion for JMOL.

1. Direct Infringement

KCI first argues that the undisputed evidence proved that two of Blue Sky's Versatile kits, "Chariker-Jeter Plus" and "Complete," directly infringed each of the twenty-one asserted claims of the '081 patent.

According to KCI, the only disputed limitation in these claims was the requirement of a screen for preventing overgrowth of tissue in the wound. KCI alleges that it was undisputed that the Aquaphor contained in both kits satisfied this limitation. KCI relies primarily on the testimony of its expert, Dr. Orgill, who argued that Aquaphor "looks like a screen," "has the semi-rigid properties described in the patent," and is used "to restrain overgrowth of granulation tissue and help provide even distribution of the suction." According to KCI, a reasonable jury could not have found for Blue Sky because Blue Sky never presented any evidence that Aquaphor does not prevent overgrowth.

Blue Sky responds with two grounds on which we could affirm the district court's denial of KCI's motion for JMOL. First, it argues that KCI accused eighteen products, six of which did not contain Aquaphor or anything else alleged to have satisfied the screen limitations, but then stipulated to a verdict form that did not differentiate between the various kits. Blue Sky contends that KCI thus treated infringement as an "all or nothing matter" and cannot now complain about the lack of specificity in the verdict. We need not decide the viability of this "all or nothing" theory, which is contested by KCI, because Blue Sky's second argument, that there was indeed a dispute over whether Aquaphor served to prevent overgrowth, is determinative.

Blue Sky cites the testimony of co-founder Tim Johnson, who explained to the jury that Aquaphor is a "soft, flexible, conforming gauze." Blue Sky also points

out that the jury observed Aquaphor gauze and had the opportunity to assess its rigidity. Additionally, Blue Sky cites testimony that the purpose of the Aquaphor was to prevent granulation tissue from attaching to either the foam screen or fluffed gauze that was placed in the wound, which allowed the jury to infer that Aquaphor did not prevent overgrowth. Finally, Blue Sky asserts that the jury was not required to accept Dr. Orgill's "wholly conclusory" testimony.

We decline to require the jury to accept the testimony of KCI's lone infringement witness, Dr. Orgill. The jury was instructed that it was not required to accept any particular witness's testimony, and the Fifth Circuit has made clear that the jury is entitled to disbelieve a party's expert if it chooses. *See Streber*, 221 F.3d at 726. Additionally, while Defendants' evidence may not have been overwhelming, it was nonetheless sufficient to support the jury's conclusion that KCI failed to meet its burden of proving that the Aquaphor prevented overgrowth.

2. Induced Infringement

KCI also appeals the denial of its motion for JMOL that Blue Sky induced infringement of claims 13, 14, and 29 of the '643 patent, each of which is a method claim that recites the use of intermittent suction. Importantly, none of these claims require a screen for the prevention of overgrowth. KCI points out that the Versatile manual explains that it "is designed for operation in two suction modes—*continuous* and *intermittent*." Additionally,

KCI alleges, Blue Sky told customers that "pressure can be altered . . . to an intermittent setting" and gave express instructions to "[s]elect continuous or intermittent suction mode." KCI cites testimony from a Blue Sky witness that "[m]any of our patients have pain with the intermittent use" as further proof that customers actually followed these instructions. Finally, at trial, KCI presented a statement from one of Blue Sky's distributors that Blue Sky told it that intermittent pressure was "[s]ometimes successful."

Blue Sky does not dispute that the Versatile is capable of using intermittent suction. Instead, Blue Sky argues that the jury's verdict is correct because KCI failed to prove both actual direct infringement and that Blue Sky had the requisite intent for inducement. With respect to direct infringement, Blue Sky argues that when the testimony KCI relies on—"many of our patients have pain with intermittent use"—is read in context, it is unclear whether the witness, a nurse with thirty years of experience using negative pressure wound therapy, was referring to use of the Versatile or use of KCI's commercial embodiment, the VAC. According to Blue Sky, such ambiguous testimony cannot support, let alone require, an inference of direct infringement. Blue Sky also argues that the product manuals and other circumstantial evidence, without more, are insufficient to prove infringement as a matter of law under *Moleculon Research Corp. v. CBS, Inc.*, 793 F.2d 1261, 1272 (Fed. Cir. 1986). Finally, Blue Sky argues that testimony from its principals, Tim Johnson and Richard Weston, provided substantial evidence to

support the jury's finding that Blue Sky lacked the level of intent necessary for inducement.

To prove induced infringement, the plaintiff must prove both direct infringement and "that the defendant possessed specific intent to encourage another's infringement." *DSU Med. Corp. v. JMS Co.*, 471 F.3d 1293, 1306 (Fed. Cir. 2006) (en banc in relevant part). We conclude that substantial evidence supports a finding that Blue Sky lacked the necessary intent. Tim Johnson testified that Blue Sky never intended to infringe KCI's patents. Richard Weston testified that he thought that because the Versatile simply performed the Chariker-Jeter method, which was in the public domain, KCI's patents could pose no barrier to Blue Sky entering the market. KCI may be correct that "practicing the prior art" is not a defense to patent infringement. *See Ecolab Inc. v. Paraclipse, Inc.*, 285 F.3d 1362, 1377 (Fed. Cir. 2002). However, it does not follow that a defendant's belief that it can freely practice inventions found in the public domain cannot support a jury's finding that the intent required for induced infringement was lacking. The jury heard Blue Sky's founders explain why they did not believe they were infringing and had the opportunity to assess their credibility. We find no basis to overturn the jury's decision with respect to inducement.

Appendix A

E. KCI's Motion for a New Trial

In the alternative to its motion for JMOL, KCI requests a new trial on infringement. In the Fifth Circuit, the district court's denial of a motion for a new trial is reviewed for abuse of discretion. *Industrias Magromer Cueros y Pieles S.A. v. La. Bayou Furs Inc.*, 293 F.3d 912, 924 (5th Cir. 2002).

KCI alleges that Defendants' "practicing the prior art" defense, comparisons of the Versatile to the VAC, and "blatant class-warfare arguments," including references to KCI's wealth and the need for an inexpensive alternative to the VAC, prejudiced the jury and resulted in an incorrect verdict.

Blue Sky responds that any comparisons between the Versatile and the Chariker-Jeter prior art references were relevant to rebut KCI's allegations of copying and willful infringement, to prove lack of intent to induce infringement, and to impeach KCI's expert's unsubstantiated distinctions between the gauze in the prior art and the gauze used with the Versatile. Similarly, Blue Sky asserts that the comparisons between the VAC and the Versatile were relevant in response to KCI's allegations that Blue Sky blatantly copied the VAC. Finally, Blue Sky argues that its references to KCI's wealth were relevant to prove the bias of KCI's witnesses and respond to KCI's arguments that Blue Sky was more interested in profits than patients.

We agree with Defendants and the district court that the arguments to which KCI objects had proper uses or were made in response to issues raised by KCI. The district court expressly found that Defendants' arguments did not amount to class warfare. Additionally, the jury was specifically instructed that it should not treat anyone unfairly based on wealth. Accordingly, we find no abuse of discretion in the court's denial of KCI's motion for a new trial.

III. CONCLUSION

For the foregoing reasons, we affirm the district court's denial of Defendants' motion for JMOL of obviousness and its determinations that certain claim terms were not indefinite. We also deny Defendants' request for a new trial on obviousness. With respect to KCI's cross-appeal, we affirm the district court's denial of KCI's motion for JMOL of infringement and its request for a new trial on infringement.

AFFIRMED.

Appendix A

UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

2007-1340, -1341, -1342

KINETIC CONCEPTS, INC., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences,

Plaintiffs-Cross Appellants,

v.

BLUE SKY MEDICAL GROUP, INC.,

Defendant-Appellant,

and

RICHARD S. WESTON,

Defendant-Appellant,

and

MEDELA AG and MEDELA, INC.,

Defendants-Appellants.

Appeals from the United States District Court for the Western District of Texas in case no. 03-CV-0832, Judge W. Royal Furgeson, Jr.

Appendix A

DYK, *Circuit Judge*, dissenting.

I respectfully dissent from the majority's holding that affirms the judgment that the claims are nonobvious. In my view, the majority improperly holds that the claim term "wound" can be limited to the disclosed embodiments in the specification, and, having done so, then misreads the specification as showing only embodiments treating harm to the surface of the body or skin wounds. Under the correct construction of this claim term, the asserted claims of U.S. Patent Nos. 5,636,643 ("'643 Patent") and 5,645,081 ("'081 Patent") would have been obvious.[1]

I

The proper construction of the term "wound" was extensively disputed pre-trial. Defendants Medela AG and Medela, Inc. ("Defendants") argued that "wound" should be construed according to its plain meaning as "injury." Defendants alternatively argued that "wound" should be construed as found in *Stedman's Medical Dictionary* (26th ed.): "(1) trauma to any of the tissues of the body, especially that caused by physical means and with interruption of continuity [or] (2) a surgical incision."

Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health

1. The asserted claims are claims 1-3, 6-8, 11-14, 16, 26-29, and 32 of the '643 patent, and claims 1, 3, 5, 8, 9, 11-13, 27, 31, 33, 36, 37, 54, 56, 58, 61, 62, and 64-66 of the '081 patent.

Sciences ("Plaintiffs") argued that "treating a wound" should not be construed at all because it is well within the common experience and understanding of every juror. Plaintiffs argued in the alternative that "wound" should be construed as "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." Although both parties introduced expert reports on claim construction to the district court, neither party relies on these expert reports on appeal.

Initially, the district court construed "wound" as "injury." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832, at 5 (W.D. Tex. June 28, 2005) ("Order *Construing Patent '643 Terms*"). However, after approximately ten days of trial, the district court decided *sua sponte* that it would adopt the Plaintiffs' approach and not instruct the jury on the proper construction of "wound." *Kinetic Concepts, Inc. v. Blue Sky Med. Corp.*, No. 03-CV-0832 (W.D. Tex. June 29, 2006) ("*Second Amended Order Construing Patent '643 and '081 Claim Terms*").

At trial, Plaintiffs argued the definition of "wound" to the jury in an effort to distinguish the prior art, particularly the public uses of Chariker and Jeter that involved applying negative pressure to surgical incisions including both a hole in the skin and a "fistula" or hole in an internal organ. Plaintiffs argued to the jury that a "fistula" was distinct from a "wound," and that the

purpose of the public uses of Chariker and Jeter was "fistula drainage" as opposed to "wound healing."[2]

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2. In opening and closing arguments, Plaintiffs attempted to distinguish the public uses of Chariker and Jeter by focusing on the fact that the method was usually used when there was a fistula: "this [Chariker-Jeter] is about fistulas, not about the wounds that we are talking about," J.A. 200862; "Remember Chariker-Jeter is healing—is drainage, not healing. Chariker-Jeter is fistula only," J.A. 205656; "Now, let's talk about Chariker-Jeter and I will repeat myself 400 times and I will shut up. Chariker-Jeter, fistulas, fistulas, fistulas, fistulas. It's about drainage," J.A. 205665. The testimony of Plaintiffs' expert witness on validity, Dr. Orgill, is also illustrative:

> Q: Is that wound healing?
>
> A: No. That's fistula drainage.
>
> Q: And why isn't that wound healing?
>
> A: Well, Chariker-Jeter describes that they stop this device when the fistula closes. And usually these devices take about 16 days, that's what they describe in their article, for this nasty fluid to stop coming out. And after that, when the fistula closes, then that's when the wound healing or the rest of the wound can start to heal.

J.A. 204932-35. Cross-examination on the definition of wound included an answer from this witness that "[v]ery often people with the definition of tissue would separate tissues from organs, so, in other words, many people in their definition of tissue

(Cont'd)

II

The district court's failure to construe the term "wound" was a clear error. We have held that "[w]hen the parties raise an actual dispute regarding the proper scope of [the patent] claims, the court, not the jury, must resolve that dispute." *O2 Micro Int'l Ltd. v. Beyond Innovation Tech. Co.*, 521 F.3d 1351, 1360 (Fed. Cir. 2008). It is improper to argue claim construction to the jury because the "risk of confusing the jury is high when experts opine on claim construction." *CytoLogix Corp. v. Ventana Med. Sys., Inc.*, 424 F.3d 1168, 1172-73 (Fed.Cir. 2005); *see Sundance, Inc. v. DeMonte Fabricating Ltd.*, 550 F.3d 1356, 1364 n. 6 (Fed. Cir. 2008). In this case, the definition of the term "wound" was central to the case and a primary focal point of the *Markman* hearing; as a result, the court should have construed the term "wound."

The appellees do not dispute that it was error to fail to construe wound, instead claiming that the issue "need not be resolved, however, since any error was harmless" under the claim construction now adopted by the majority. Appellee's Br. 51. The majority agrees.

(Cont'd)

might not consider, for example, a kidney to be a tissue. I understand some people would, but some people would separate organ from tissues." J.A. 205092. Testimony by an inventor also focused on this distinction: "It's totally different. They're treating drainage. We're treating a wound. . . . We're treating to close a wound. They're treating to control the fistula."

However, there is no suggestion by either the majority or the appellees that the verdict could be sustained under the appellants' proposed construction. Thus, the crucial question is whether the majority's claim construction is correct. In my opinion it is not.

III

The majority construes "wound" to mean "tissue damage to the surface of the body, including the epithelial and subcutaneous layers" because "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 1019. It is the words of the claim that define the scope of the patent. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc). The words are generally construed according to their ordinary and customary meaning, that is, "the meaning that the term would have to a person of ordinary skill in the art in question at the time of the invention." *Id.* at 1313. This meaning is to be interpreted in the context of the entire patent, including the specification. *Id.* However, it is improper to import limitations from the specification into the claims where there is no indication that the specific examples in the specification are intended to be strictly coextensive with the claim. *Id.* at 1323.

The majority holds that the term "wound" should be understood as limited to damage to tissues near the surface of the body, particularly the skin, and should not include damage to organs. The majority points to no medical dictionary or other extrinsic evidence

supporting this claim construction. The specification does not define "wound" or provide any examples of the types of harms that would *not* qualify as wounds under the claim terms. Nor does the specification state that the examples listed in the specification were intended to describe the entire invention. *See SciMed Life Sys., Inc. v. Advanced Cardiovascular Sys., Inc.*, 242 F.3d 1337, 1343-44 (Fed. Cir. 2001) (specification described "all embodiments of the present invention"). Nonetheless, the majority concludes that, because the specification examples supposedly only include descriptions of damage to the skin, the specification limits the kinds of wounds encompassed by the claim. In my view, our decision in *Phillips* bars us from construing the claims as limited by the specification examples, and the majority's approach is without support in our post-*Phillips* cases.

But even if the examples could limit the claims, in my view the examples here are not limiting, and indeed the specifications confirm the inappropriateness of the majority's construction. The specifications of both patents make clear that the examples are merely "illustrative."[3] The specifications also state that the

3. The '081 Patent specification states: "[t]hese examples are provided for illustrative purposes only and are not to be taken as limiting," col.5 ll.47-49, and "[t]he foregoing examples are illustrative of the present invention, and are not to be construed as limiting thereof," col.9 ll.46-48. *See also* '643 Patent col.21 ll.43-45 ("The terms and expressions which have been employed are used as terms of description and not of limitation.").

invention is "useful for treating a variety of wounds." '643 Patent col.12 ll.41-42. "Wounds that have exhibited positive response to treatment by the application of negative pressure *include* infected open wounds, decubitus ulcers, dehisced incisions, partial thickness burns, and various lesions to which flaps or grafts have been attached." '643 Patent col.2 ll.58-62. (emphasis added). The use of the illustrative and open language of "include" demonstrates that there may be other types of wounds that the specification does not expressly point out, but that would nonetheless be covered by the claim term "wound." *See SanDisk Corp. v. Memorex Prods., Inc.*, 415 F.3d 1278, 1284 (Fed. Cir. 2005); *Amgen Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1344-45 (Fed. Cir. 2003). Throughout the specifications, the term "wound" is used only in this broad and inclusive way. *See, e.g.*, '643 Patent col. 13 ll.23-29.

Moreover, the majority is incorrect in asserting that "[a]ll of the examples described in the specification involve skin wounds." Maj. op. at 1019. In fact, a number of examples illustrate that the wounds at issue are not merely skin wounds but deep wounds that include damage to more than the skin, such as wounds in which bone was exposed, '643 Patent col.19 ll.35-39, col.20 ll.23-27, large quantities of fluid were draining, '643 Patent col.19 ll.23-26, surgical incisions cut through the abdominal wall and did not heal, '643 Patent col.19 ll.55-65, or bone was infected, '643 Patent col.20 ll.49-61. *See also* '081 Patent col.8 ll.58-67, col. 9 ll.19-27, ll.35-41. These examples disclose wounds with far more than mere "damage to the epithelial and subcutaneous

layers," suggesting that other kinds of damage, including fistulae caused by surgical incision, would be within the definition of "wound" as used in the claim. These examples explicitly identify benefits achieved in the healing of interior tissue. For example, '643 Patent col.19 ll.55-65 and '081 Patent col.8 ll.60-65 describe increased healing of the abdominal wall by granulation tissue in and through Prolene mesh, and '643 Patent col.19 ll.23-26 and '643 Patent col.20 ll.25-35 describe draining fluid from interior infections.[4]

In view of the inclusive language and examples of the specification, I would find a dictionary frequently used by a person of ordinary skill in the art significant in understanding the meaning of "wound" in the claim. *See Phillips*, 415 F.3d at 1322-23 ("[J]udges are free to consult dictionaries and technical treatises . . . when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents." (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d

4. To be sure, one of the identified purposes of the invention applies only to the skin. *See* '643 Patent col.1 ll.20-25 (describing the "zone of stasis" in which blood flow to the skin around a wound is restricted as a problem addressed by the invention). However, we have held that "[t]he court's task is not to limit claim language to exclude particular devices because they do not serve a perceived 'purpose' of the invention. . . . An invention may possess a number of advantages or purposes, and there is no requirement that every claim directed to that invention be limited to encompass all of them." *E-Pass Techs., Inc. v. 3Com Corp.*, 343 F.3d 1364, 1370 (Fed. Cir. 2003).

1576, 1584 n. 6 (Fed. Cir. 1996))). The definition of "wound" provided by *Stedman's*, an accepted medical dictionary,[5] includes "trauma to any of the tissues of the body" and "surgical incision." In light of the disclosures of the specifications and the additional support of the dictionary, in my view the term "wound" as used in the claim includes fistulae caused by surgical incision.

IV

The uncontroverted evidence demonstrates obviousness under the construction that I would adopt. Extensive evidence was presented at trial of public uses to heal fistula's caused by surgical incisions, by both Dr. Chariker and Dr. Jeter.[6] There was no testimony to the contrary, nor is there any contention that the claims would be nonobvious if "wound" were construed as I suggest. Under the correct claim construction the undisputed evidence demonstrates that the claims would have been obvious.

For the foregoing reasons, I respectfully dissent.

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5. Plaintiffs' expert witness testified that *Stedman's* is a medical dictionary used in the profession. Plaintiffs even referenced the definition of wound provided by *Stedman's* in filings to the FDA describing the full scope of wounds that could be treated by their device.

6. The parties do not dispute that this evidence meets the definition of a prior art public use under 35 U.S.C. § 102(b).

APPENDIX B — VERDICT

Question 17

OBVIOUSNESS OF THE '643 PATENT

Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '643 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 17, please refer to pages 25-34 and 38-45 of the Court's Instructions.

Please answer "Yes" or "No" in each of the blanks below:

Claim 1	No	Claim 13	No
Claim 2	No	Claim 14	No
Claim 3	No	Claim 16	No
Claim 6	No	Claim 26	No
Claim 7	No	Claim 27	No
Claim 8	No	Claim 28	No
Claim 11	No	Claim 29	No
Claim 12	No	Claim 32	No

Please proceed to the next question.

Appendix B

OBVIOUSNESS OF THE '081 PATENT

Have the Defendants proven by clear and convincing evidence that the invention claimed in any of the following claims of the '081 patent would have been obvious to a person of ordinary skill in the art at the time the invention was made, in light of the prior art? In answering Question No. 18, please refer to pages 25-34 and 38-45 of the Court's Instructions.

Please answer "Yes" or "No" in each of the blanks below:

Claim 1	No	Claim 36	No
Claim 3	No	Claim 37	No
Claim 5	No	Claim 54	No
Claim 8	No	Claim 56	No
Claim 9	No	Claim 58	No
Claim 11	No	Claim 61	No
Claim 12	No	Claim 62	No
Claim 13	No	Claim 64	No
Claim 27	No	Claim 65	No
Claim 31	No	Claim 66	No
Claim 33	No		

Please proceed to the next question.

APPENDIX C — FINAL JUDGMENT OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, SAN ANTONIO DIVISION FILED AUGUST 29, 2006

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

No. SA-03-CA-0832 – RF

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC. and WAKE FOREST UNIVERSITY HEALTH SCIENCES

Plaintiffs,

v.

BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., and PATIENT CARE SYSTEMS, INC.

Defendants.

FINAL JUDGMENT

On June 1, 2006, the court called this case for trial before a duly impaneled and sworn jury. Plaintiffs Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences ("Plaintiffs") appeared in person through their corporate representatives and counsel of record. Defendants

Appendix C

BlueSky Medical Corporation, Medela AG, and Medela, Inc. appeared in person through their corporate representatives and counsel of record. Defendant Richard Weston appeared personally and through his counsel of record. Defendants BlueSky Medical Corporation, Richard Weston, Medela AG, and Medela, Inc. are referred to collectively herein as "Defendants."

Prior to trial, the Court ruled on certain claims brought by the parties. Those rulings are incorporated into this Final Judgment. Interrogatories were submitted to the jury by the Court on the remaining claims. The jury answered those interrogatories.

The Court, having considered the verdict and all things both to the law and the evidence, now enters judgment in this case. It is hereby ORDERED, ADJUDGED, AND DECREED that:

1. The Plaintiffs take nothing on their claims against Defendants; and

2. Medela, Inc. and Medela AG take nothing on their counterclaims against the Plaintiffs for declarations of patent invalidity and patent unenforceability

It is so ORDERED.

Signed this 29th day of August, 2006.

s/ Royal Furgeson
ROYAL FURGESON
UNITED STATES DISTRICT JUDGE

APPENDIX D — ORDER DENYING DEFENDANT MEDELA'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR, ALTERNATIVELY, A NEW TRIAL ON PATENT INVALIDITY AND DEFENDANT BLUESKY'S MOTION FOR NEW TRIAL OF THE UNITED STATES DISTRICT COURT FOR THE WESTERN DISTRICT OF TEXAS, SAN ANTONIO DIVISION FILED APRIL 4, 2007

UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF TEXAS
SAN ANTONIO DIVISION

No. SA-03-CV-832-WRF

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., AND WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Plaintiffs,

v.

BLUESKY MEDICAL CORPORATION, MEDELA AG, MEDELA, INC., AND PATIENT CARE SYSTEMS, INC.,

Defendants.

Appendix D

ORDER DENYING DEFENDANT MEDELA'S RENEWED MOTION FOR JUDGMENT AS A MATTER OF LAW, OR, ALTERNATIVELY, A NEW TRIAL ON PATENT INVALIDITY AND DEFENDANT BLUESKY'S MOTION FOR NEW TRIAL

BEFORE THE COURT is Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity (Docket No. 791), filed September 13, 2006 and Plaintiffs' Response (Docket No. 816), filed under seal October 23, 2006. After due consideration of the parties' briefing, the facts, and the applicable law, the Court is of the opinion that Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity should be DENIED. To the extent that Defendant BlueSky's Motion for New Trial (Docket No. 797) seeks the same relief as Medela, BlueSky's Motion is similarly DENIED.

FACTUAL AND PROCEDURAL BACKGROUND

Defendants Medela AG and Medela, Inc. (collectively "Medela") filed this Motion for Judgment as a Matter of Law or New Trial following a six-week long jury trial concerning patent invalidity, unenforceability, and infringement. At the end of trial, the jury concluded that Plaintiffs take nothing on their patent infringement claims and Defendant Medela take nothing on its counterclaims of patent invalidity and patent unenforceability. Due to the length of both the

trial and the transcript in this case, the Court is well aware of the pertinent facts, which will not be reiterated here.

STANDARD OF REVIEW

A. Standard of Review for Judgment as a Matter of Law

"A motion for judgment as a matter of law . . . in an action tried by jury is a challenge to the legal sufficiency of the evidence supporting the jury's verdict."[1] A court must consider all the evidence before the jury and draw all reasonable inferences in favor of the nonmovant, and cannot weigh the evidence or make credibility determinations.[2] A court should enter judgment as a matter of law when "the facts and references point so strongly and overwhelmingly in the movant's favor that reasonable jurors could not reach a contrary conclusion."[3]

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1. *Flowers v. S. Reg'l Physician Servs.*, 247 F.3d 229, 235 (5th Cir. 2001) (internal quotations omitted) (quoting *Ford v. Cimarron Ins. Co., Inc.*, 230 F.3d 828, 830 (5th Cir. 2000)).

2. *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150-51 (2000).

3. *Coffel v. Stryker Corp.*, 284 F.3d 625, 630 (5th Cir. 2002).

B. Standard of Review for a New Trial

Trial judges may grant new trials "for any of the reasons for which new trials have heretofore been granted in actions at law in the courts of the United States."[4] This broad authority includes granting a new trial if "the verdict is against the great-not merely the greater-weight of the evidence."[5] The "great weight of the evidence" standard is not easily met, but a verdict can be against the "great weight of the evidence," and thus justify a new trial, even if there is substantial evidence to support it.[6] In ruling on a motion for new trial, the trial court may weigh the evidence. To grant a motion for new trial, however, the trial judge "must be convinced that the verdict is against the great weight of the evidence."[7]

DISCUSSION

Because a patent is presumed valid, the quantum of proof required at trial to find invalidity is clear and

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4. FED. RULE CIV. P. 59(a).

5. *Conway v. Chem. Leaman Tank Lines, Inc.*, 610 F.2d 360, 362 (5th Cir. 1980) (per curiam) (citing *Spurlin v. Gen. Motors Corp.*, 528 F.2d 612, 620 (5th Cir. 1976)).

6. *Shows v. Jamison Bedding, Inc.*, 671 F.2d 927, 930-31 (5th Cir. 1982).

7. *Id.*

convincing evidence.[8] Thus, to grant judgment as a matter of law, Defendant Medela must meet the difficult burden of proving that no reasonable jury could have decided that Medela failed to meet its clear and convincing burden. To grant a new trial, Medela must show that the great weight of evidence clearly and convincingly proved invalidity.

Attempting to meet this difficult burden, Medela argues both in its original motion and in its supporting reply, that the jury's findings are contrary to the great weight of the evidence in three areas: (1) Medela proved by clear and convincing evidence that prior public uses, public knowledge, and sales of the claimed negative pressure systems and devices invalidated the asserted claims of the patents-in-suit; (2) Medela proved by clear and convincing evidence that prior art anticipated or made obvious each of the asserted claims of the patents-in-suit; and (3) if the Court does not grant judgment as a matter of law that the asserted claims are invalid, Medela seeks a new trial on patent invalidity that would include the testimony of David Tumey and Marie McGregor. The Court explains each of these assertions and Plaintiffs' responses, in turn.

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8. 35 U.S.C. § 282 (2002) ("A patent shall be presumed valid."); *Sid W. Richardson, Inc. v. Bryan*, 144 F. Supp. 916, 919 (S.D. Tex. 1956), *affirmed*, 254 F.2d 191, *cert. denied*, 358 U.S. 815.

Appendix D

A. Defendant Medela's Arguments

1. Prior public use, knowledge, and sales

Under 35 U.S.C. § 102, a patent is invalid "if the invention was known or used by others in this country . . . before the invention thereof by the applicant for patent, or . . . [if] the invention was . . . in public use or on sale in this country, more than one year prior to the date of the application for patent."[9] Defendant Medela argues that clear and convincing evidence shows that prior public use invalidates one or more of the asserted claims of the patents-in-suit. This clear and convincing evidence was the testimony of four witnesses claiming they used the claimed invention before the critical date of the patents-in-suit. According to Medela, Plaintiffs failed to rebut this testimony, thereby warranting judgment as a matter of law as to its invalidity defense.

2. Prior art anticipated or made obvious asserted claims

A patent is invalid "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains."[10] Defendant Medela asserts

9. 35 U.S.C. § 102(a -b) (2002).

10. 35 U.S.C. § 103 (2004).

that the contested claims of the patents-in-suit are invalid because they are obvious. Medela's evidence is two doctors testifying about state-of-the-art wound care in November 1990, and a list of at least seven articles containing prior art references. The doctors testified that various claims in the patents would have been obvious to a person of ordinary skill in the art considering the combination of another patent and any one of these seven prior-art articles. In response to this detailed testimony, Plaintiffs presented "conclusory testimony" of two doctors who had been funded by KCI in the past. According to Defendant Medela, this testimony did not rebut Medela's evidence in any meaningful way, warranting judgment as a matter of law.

3. New trial including testimony of David Tumey and Marie McGregor

David Tumey was the head of KCI's Research and Development department and read one of the prior-art articles during his tenure at KCI. The Court disallowed David Tumey's testimony at trial. The Court also prevented the testimony of Marie McGregor regarding her use of prior-art treatments for wounds using negative pressure in combination with dressings.

To determine whether the exclusion of this evidence warrants a new trial, the Court should follow a three-step analysis and assess: (1) the probability that the evidence would have changed the outcome of the trial; (2) whether the evidence could have been discovered earlier through the moving party's due diligence; and

(3) whether the evidence is merely cumulative or impeaching.

(1) Probability that evidence would have changed the outcome

Defendant Medela rather conclusively states that had the jury heard Tumey's testimony concerning the similarity of prior art to the claimed inventions, the outcome of the trial would have changed. Similarly, McGregor's testimony is uniquely influential because it concerns her use of negative pressure wound treatment in the late 1980's.

(2) Whether the evidence could have been discovered earlier through the moving party's due diligence

Defendant Medela says that KCI failed to disclose the scope of Tumey's knowledge properly such that Tumey's testimony was properly first discovered during trial but before the jury began deliberations. It is not clear when Medela learned of McGregor's testimony.

(3) Whether the evidence is merely cumulative or impeaching

Defendant Medela argues this testimony is not cumulative because Tumey has a unique perspective on the prior-art reference. Rather than being cumulative, Tumey's analysis that the prior-art article discloses a device that is at least similar to KCI's patent uniquely

contrasts Plaintiffs' argument that the prior-art article has "nothing to do with our case." Similarly, McGregor's testimony is not cumulative because no one else can testify as to McGregor's personal use.

B. Plaintiffs' Response

Plaintiffs respond on two grounds. First, Plaintiffs argue that legally sufficient evidence supports the jury's verdict. As part of this argument, Plaintiffs argue that Defendant Medela's request for judgment as a matter of law must be denied because: (1) Plaintiffs presented compelling evidence of patent validity; (2) Medela's witnesses lacked credibility and credentials; (3) Medela's "public use" evidence lacked requisite specificity and corroboration; and (4) the evidence established that no prior art anticipated or rendered obvious any asserted patent claim. As a second ground for denying Defendant Medela's motion, Plaintiffs contend that the exclusion of Tumey's and McGregor's testimony does not warrant a new trial.

1. Legally sufficient evidence supports the jury's verdict.

Plaintiffs couch their argument on the grounds that in this case, the parties presented dueling experts, and it is the jury's responsibility to determine the credibility of the experts. Because Defendant Medela's experts were not credible and compelling, judgment as a matter of law is inappropriate.

Appendix D

(1) Compelling evidence of patent validity.

Plaintiffs argue that they presented compelling evidence of patent validity. Two doctors explained the invention process, including one doctor who said that Plaintiffs' invention was the greatest advance in plastic surgery in the past ten years. Dr. Orgill also explained the differences between the claimed invention and the prior art. Dr. Orgill is an especially important witness for Plaintiffs, as he received the Court's praise regarding his impressive credentials. Two doctors also testified about the novelty of the claimed invention. This is compelling evidence of patent validity.

(2) Lack of credibility

Defendant Medela's witnesses, on the other hand, lacked credibility and credentials, preventing them from meeting the "clear and convincing" burden. Plaintiffs point out that one defense expert had never read a patent and had done no research on negative pressure wound therapy. Additionally, the expert's credibility was impugned by the testimony of BlueSky's founder, who admitted that the patent-in-suit was different than the prior art. Another defense expert lacked credibility because he changed his testimony from one day to the next.

(3) No collaboration of public use

Further, Plaintiffs argue that because Defendant Medela's alleged prior public use argument lacks

corroboration, it could not have met the "clear and convincing" standard. A party asserting invalidity based on prior public use must establish that "the subject of the barring activity met each of the limitations of the claim, and thus was an embodiment of the claimed invention."[11] Generally, oral testimony of prior public use must be corroborated in order to invalidate a patent.[12] As a result of the distrust of oral testimony, ideal corroboration is evidenced by contemporaneous physical records made at the time of the alleged prior invention.[13]

All four of the doctors required corroboration because they were testifying about their own

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11. *Juicy Whip Inc. v. Orange Bang, Inc.*, 292 F.3d 728, 737 (Fed. Cir. 2002).

12. *Id.* (citing *Finnigan Corp. v. Int'l Trade Comm'n*, 180 F.3d 1354, 1366-68, 51 USPQ2d 1001, 1010-11 (Fed. Cir. 1999)); *The Barbed Wire Patent*, 143 U.S. 275, 284-85 (1892):

> [T]he very fact . . . that almost every important patent, from the cotton gin of Whitney to the one under consideration, has been attacked by the testimony of witnesses who imagined they had made similar discoveries long before the patentee had claimed to have invented his device, has tended to throw a certain amount of discredit upon all that class of evidence, and to demand that it be subjected to the closest scrutiny.

Id.

13. *Id.* at 743.

anticipatory activities, but Medela did not produce any corroborating physical records. According to Plaintiffs, the presentation of the photographs and the cross-collaboration of the doctors is insufficient collaboration. In addition to the collaboration argument, Plaintiffs also contend that Medela's witness's earlier use was neither commercial nor public—the negative pressure wound care was experimental and not covered by Medicaid.

(4) Anticipation and Obviousness

Plaintiffs' final argument that legally sufficient evidence supports the jury's verdict is that the evidence establishes that no prior art anticipates or renders obvious any asserted patent claim. Specifically, the evidence shows that none of the prior-art references contains all the limitations of any asserted patent claim, such that Medela lacks the clear and convincing evidence necessary to find anticipation of any claim. Moreover, Plaintiffs assert that the record is replete with indicia of nonobviousness.

2. *Exclusion of Tumey and McGregor Testimony*

Apart from their arguments against judgment as a matter of law, Plaintiffs contend that Tumey and McGregor's testimony do not warrant a new trial. First, Tumey's testimony was untimely designated and inadmissible. Defendants met with Tumey as early as 2001. Plaintiffs disclosed Tumey as a person who might have relevant knowledge on December 17, 2004. Fact discovery closed on December 9, 2005, but Medela did

not ask to depose Tumey until after the closing of fact discovery. Despite this late request, the Court allowed Tumey's deposition. Apart from this untimely deposition, Tumey's testimony concerning the similarity of patented inventions is inadmissible because Tumey is not a patent expert, but merely a lay witness.

McGregor's testimony was also properly excluded because it was untimely and uncorroborated. Defendants did not fully disclose the nature of the anticipated testimony until the time of trial. There was also no corroboration of her alleged prior use.

C. The Court's Decision

Applying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict and thus declines to disturb it. The Court finds merit in Plaintiffs' credibility arguments. It is the province of the jury—not the judge—to determine the credibility of witnesses.[14] In such a case as this, wherein highly qualified and devoted counsel represent both sides through a lengthy trial, jurors must wrestle with the credibility of lay and expert witnesses alike, whose juxtaposed opinions are often equally possible but entirely diametric. As such, while it may be true that

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14. *See, e.g., Ray v. Iuka Special Mun. Separate Sch. Dist.*, 51 F.3d 1246, 1251 (5th Cir. 1995) (noting that "the assessment of the witnesses' credibility is clearly a jury function"); *Smith v. Harrah's New Orleans Mgmt. Co.*, No. 05-30096, 2007 WL 98994, at *5 (5th Cir. Jan. 16, 2007) (citing *Hardy v. Wal-Mart Stores, Inc.*, 237 F.3d 632, at *1 (5th Cir. 2000)).

Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors.

It is difficult for the Court to assail a verdict such as the one here, wherein the jurors, having been presented with an abundance of evidence, determined that Defendants failed to meet their burden of proof. A reasonable jury was entitled to believe Plaintiffs' evidence and to disbelieve Defendants' evidence if it chose to. In this case, it clearly did so. The Court finds that because the allocation of credibility was within the province of the jury, Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity must be DENIED.

CONCLUSION

Legally sufficient evidence supports the jury's verdict. Accordingly, the Court DENIES Defendant Medela's Renewed Motion for Judgment as a Matter of Law, or, in the Alternative, a New Trial on Patent Invalidity (Docket No. 791). Additionally, to the extent that Defendant BlueSky's Motion for New Trial (Docket No. 797) seeks the same relief as Defendant Medela, Defendant BlueSky's Motion for New Trial is also DENIED.

It is so ORDERED.

Signed this 4th day of April, 2007.

s/ Royal Furgeson
ROYAL FURGESON
UNITED STATES DISTRICT JUDGE

APPENDIX E — 35 U.S.C. § 103(a)

§ 103. Conditions for patentability; non-obvious subject matter

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

* * * *

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(4)

No. 09-198

Supreme Court, U.S.
FILED
OCT 16 2009
OFFICE OF THE CLERK

IN THE
Supreme Court of the United States

MEDELA AG AND MEDELA, INC.,
Petitioners,

v.

KINETIC CONCEPTS, INC., ET AL.,
Respondents.

On Petition for Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

RESPONDENTS' BRIEF IN OPPOSITION TO PETITION FOR WRIT OF CERTIORARI

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October 16, 2009

QUESTION PRESENTED

The ultimate judgment of obviousness is a legal issue, but it is well recognized that any underlying factual issues are for the jury. Here, Medela consented to having the jury render a general verdict on obviousness—and did not ask for special interrogatories on any underlying factual issue—and the jury rejected Medela's obviousness claim. On appeal, the Federal Circuit, consistent with this Court's precedent, presumed that the jury had resolved the factual issues underlying obviousness in KCI's favor, applied the substantial-evidence standard of review, and determined that the verdict of nonobviousness was legally correct.

The question presented is:

Whether, where the parties have *consented* to giving the issue of obviousness to the jury, it is error for the appellate court to assess the jury's verdict by presuming that the jury made factual findings in the prevailing party's favor, applying the substantial-evidence test, and examining legal questions on a de novo basis.

RULE 29.6 STATEMENT

All parent corporations and any publicly held companies that own 10 percent or more of Respondents' stock are:

Kinetic Concepts, Inc., a publicly traded company, is the parent corporation of both KCI Licensing, Inc., and KCI USA, Inc.

Invesco PLC, which owns the AIM and Invesco families of mutual funds, owns 10% or more of Kinetic Concepts, Inc., either directly or through its mutual funds.

Wake Forest University is the parent of Wake Forest University Health Sciences.

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I. PRELIMINARY STATEMENT

At its essence, Medela's[1] certiorari petition challenges the Federal Circuit's refusal to find error in the district court's decision not to substitute its fact-finding for the jury's on the issue of obviousness. But the procedures followed in the district court—including the submission of the obviousness issue to the jury with no special interrogatories—were all *with Medela's consent.* And both the district court and the Federal Circuit followed well-established law in upholding the jury's verdict that the asserted claims were nonobvious.

Following a six-week trial, the jury was instructed on Medela's obviousness defense and asked to reach a general verdict on obviousness. But rather than objecting to this procedure—as one might assume were the case from reading Medela's certiorari petition—Medela fully consented to it. Indeed, while the Federal Circuit has *encouraged* parties in Medela's position to ask for special interrogatories relating to the facts underlying a verdict on an issue such as obviousness, Medela never did that. Instead, Medela was perfectly happy entrusting the obviousness issue to the jury—until it

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[1] "Medela" is used to refer collectively to Petitioners Medela AG and Medela, Inc. The action below was also brought against Blue Sky Medical Group, Inc. ("Blue Sky"), but neither Blue Sky nor its subsequent acquirer, Smith & Nephew, Inc., is a party to Medela's certiorari petition.

returned its verdict that the asserted claims were nonobvious.

After the district court denied Medela's renewed motion for judgment as a matter of law ("JMOL"), Medela appealed and the Federal Circuit affirmed. Following this Court's precedent, the Federal Circuit thoroughly reviewed the evidence, drawing all reasonable inferences in KCI's[2] favor, and found that substantial evidence supported the jury's verdict.

Not liking that result, Medela has now come to this Court, asserting that "[u]nder Federal Circuit precedent . . . , a person accused of patent infringement has no right to independent judicial, as distinct from lay jury, determination of obviousness." Medela Pet. for Writ of Cert. ("Pet.") at i. The crux of Medela's argument is that under Federal Circuit precedent, a jury that returns a verdict on the issue of obviousness does not provide any explanation of its verdict, which makes it impossible for the court to know the underlying rationale of the jury's verdict. Thus, Medela complains that in this case, the Federal Circuit had to "assume" that the jury resolved the facts in KCI's favor, since the jury's actual findings would be "impossible to know or to determine." *Id.* at 9.

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[2] "KCI" is used to refer collectively to Respondents Kinetic Concepts, Inc., KCI Licensing, Inc., KCI USA, Inc., and Wake Forest University Health Sciences.

But the premise of Medela's argument is wrong. Under Federal Circuit precedent, a party accused of infringement (or the patentee, for that matter) can request a jury verdict form with interrogatories directed to the factual findings the jury is required to make. In fact, far from forbidding this practice (as Medela suggests), the Federal Circuit has *encouraged* parties to request the submission of factual interrogatories to the jury precisely to facilitate the review of the verdict. Here, however, Medela's counsel never asked the district court to submit special interrogatories to the jury.

Medela also mischaracterizes what happens when parties request a general verdict from the jury, whether regarding obviousness or any other issue that is ultimately a question of law based on underlying facts. In that situation, the reviewing court has no choice but to assume the jury resolved the underlying factual issues in the prevailing party's favor, and its review can only look to whether the presumed factual findings are supported by substantial evidence. To review the jury's verdict in any other way would usurp the jury's constitutional fact-finding role.

KCI respectfully requests that the Court deny Medela's petition for a writ of certiorari.

II. FACTUAL BACKGROUND

A. The Invention

The invention covered by the patents-in-suit is a "negative pressure wound therapy" ("NPWT") system. The invention is often used to treat chronic wounds, which are wounds that do not heal and stay open for weeks, months, and sometimes even years. Before the invention, patients with chronic wounds had few treatment options, all of which were both painful and largely ineffective, frequently ending in amputation. But the NPWT system invented by Drs. Louis Argenta and Michael Morykwas—colleagues at Wake Forest University School of Medicine—changed wound-care treatment forever.

Despite initial skepticism from their peers, the inventors tested their device on patients with severe chronic wounds. To everyone's surprise, the wounds healed. Today, the invention's commercial embodiment—the V.A.C.® therapy system ("VAC") sold by KCI—has been used to treat more than a million patients and is used in virtually every major medical center in the developed world. In 2006, a nationwide group of senior plastic surgeons recognized the VAC as the biggest advance in their field in the preceding decade.

B. The District Court Proceedings

After Blue Sky released an NPWT product, KCI brought a patent-infringement suit against both Blue Sky and its vacuum-pump supplier, Medela. At

trial, Blue Sky and Medela raised numerous defenses, including obviousness over various prior-art techniques, most of which had already been considered by the PTO before issuing the patents-in-suit.

During the six-week trial, the parties presented competing expert testimony regarding validity. KCI's expert testified that each prior-art technique lacked at least one limitation of each asserted claim. For example, the key contested limitation found in all of the claims was "treating a wound with negative pressure," and this limitation served as the focal point of the parties' trial presentations.

KCI's expert, for instance, explained in detail why the prior art that defendants relied on lacked this limitation. Among other things, he testified that Medela's two main prior-art techniques, described in references authored by Chariker-Jeter and Davydov, disclosed systems that drained, respectively, a fistula (i.e., a hole between two organs such as the skin and the intestines) and a pocket of pus inside the breast. Because neither a fistula nor a "pus pocket" is a "wound" within the meaning of the asserted patents, KCI's expert concluded that neither reference disclosed "treating a wound." KCI's expert also explained why the other prior-art references, Svedman and Johnson, did not render the asserted claims obvious. As he testified, Svedman taught treating a wound with an irrigation device, and Johnson taught treating a wound with a

skin graft. Thus, KCI's expert concluded that neither reference taught "treating a wound *with negative pressure*." KCI also presented extensive testimony supporting secondary considerations of nonobviousness, including initial skepticism, unexpected results, long-felt need, commercial success, peer recognition, and copying.

The court's instructions to the jury included over seven pages devoted to the obviousness issue. The instructions thoroughly explained the factors that the jury was to consider and the potential pitfalls to avoid in determining obviousness. For example, the instructions taught that:

> The issue is not whether the claimed invention would have been obvious to you, to me as a judge, or to a genius in the field of the invention. Rather the question is whether or not the invention would have been obvious to a person of ordinary skill in the field of the invention.

The instructions further explained that the jury "must avoid using hindsight," and must "not use the patents as a road map for selecting and combining items of prior art."

Next, the instructions focused on the four *Graham* factors (from *Graham v. John Deere Co.*, 383 U.S. 1 (1966)) and explained what facts the jury had to find for it to find the asserted claims obvious or nonobvious. And regarding the objective

indications concerning obviousness, the instructions indicated that the jury "must consider certain factors, which, if established, weigh in favor of finding that the invention would not have been obvious," but that "[n]o factor alone is dispositive."[3]

But while one might infer from Medela's discussion of the instructions on obviousness (*see* Pet. 5-6) that Medela objected to them, or at least *some* of them, that would be wrong. At no point during the trial did Medela ever object to the instructions on obviousness. In fact, at the Federal Circuit, Medela readily admitted that it *stipulated* to the instructions. Br. of Appellants, Medela AG and

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[3] Medela asserts that the jury's determinations of the *Graham* factors were "dependent on various subsidiary legal conclusions." Pet. 5-6. But the *Graham* factors are "basic factual inquiries," and each of the eight alleged "subsidiary legal conclusions" listed by Medela is either solely or principally an issue of fact. *See, e.g., Graham*, 383 U.S. at 17 (stating that the obviousness determination "lends itself to several basic factual inquiries" and then identifying the inquiries, now called the four *Graham* factors); *Kim v. ConAgra Foods, Inc.*, 465 F.3d 1312, 1326 (Fed. Cir. 2006) ("The determination of what a prior art reference discloses is a question of fact."); *TypeRight Keyboard Corp. v. Microsoft Corp.*, 374 F.3d 1151, 1157 (Fed. Cir. 2004) (stating that whether a reference is prior art "is a question of law based on underlying fact questions"); *In re GPAC, Inc.*, 57 F.3d 1573, 1577 (Fed. Cir. 1995) (stating that in determining the scope and content of the prior art, "whether a reference . . . is 'analogous' is a fact question"); *id.* at 1579-80 (reviewing the factors for determining the level of ordinary skill in the art as factual findings).

Medela, Inc. ("Medela CAFC Br.") 55 (admitting that "the parties stipulated to the jury instructions on obviousness"). Nor did Medela object to the general verdict form that asked the jury to answer "yes" or "no" to whether the asserted claims were obvious. Moreover, Medela never objected to the jury deciding the ultimate question of obviousness, Medela never suggested that the jury's verdict should be considered "advisory" only, and Medela never sought special interrogatories in which the jury would have answered specific questions relating to the factual issues underlying obviousness. Thus, despite its current complaints, at trial, Medela *consented* to the jury's role in determining obviousness.

After deliberating, the jury returned the general verdict form, answering "no" to whether defendants proved each of the claims was obvious. As Medela notes, "[t]he jury was not asked to provide, and did not provide, any explanation of these 'no' answers." Pet. 6-7. But what Medela ignores is that it never suggested that the jury *should* provide any explanation for its answers.

Medela then filed a renewed JMOL motion on the issue of obviousness, which the district court denied. The court first noted the "difficult burden" that Medela had to meet to show that no reasonable jury could have decided that Medela failed to meet its clear and convincing burden. Appendices to Pet. ("App.") 50a. Based on the extensive evidence and testimony presented by both sides, the court found that substantial evidence supported the jury's

verdict. The court properly held that "[i]t is the province of the jury—not the judge—to determine the credibility of witnesses." *Id.* at 58a. In considering the evidence, the court also noted that "while it may be true that Defendant Medela provided arguably ample evidence of patent invalidity, such evidence carries only the weight as measured by a pool of dedicated jurors." *Id.* at 58a-59a. Thus, the court considered all of the evidence presented at trial and, while appropriately deferring to the factual findings of the jury, determined that substantial evidence supported the jury's verdict. *Id.* at 58a (stating that in "[a]pplying the legal standards and upon review of the briefing, the Court finds sufficient evidence to justify the jury's verdict").

C. The Federal Circuit's Decision

On appeal to the Federal Circuit, one of Medela's arguments was that the district court had erred in denying its JMOL motion that the asserted claims were invalid as obvious.[4]

In its opinion, the Federal Circuit first considered the claim term "wound," the construction

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[4] Alternatively, Medela sought a new trial on obviousness, and Medela also challenged the district court's decision rejecting its argument that certain claim terms were invalid as indefinite. However, Medela did not challenge the district court's decision (based on the jury's verdict) that the asserted claims were not invalid as anticipated.

of which was relevant to the obviousness inquiry. Medela asserted that the term "wound" should be broadly construed (according to a medical dictionary) to encompass both traumas to any body tissue and surgical incisions. App. 13a. KCI, on the other hand, asserted that because every example in the specification describes skin wounds, the correct construction of "wound" is "tissue damage to the surface of the body, including the epithelial and subcutaneous layers." *Id.* at 14a.

The Federal Circuit agreed with KCI that the specification did not support Medela's overly broad construction of "wound." Recognizing that the parties' dispute affected only two of the prior-art techniques—Chariker-Jeter and Davydov—the court stated that:

> We agree with KCI that "wound," as used in the asserted patents, does not cover the fistulae described in the Chariker-Jeter publications and the "pus pockets" described in the Davydov references. . . . All of the examples described in the specification involve skin wounds. To construe "wound" to include fistulae and "pus pockets" would thus expand the scope of the claims far beyond anything described in the specification.

Id. at 15a (citation omitted).

Turning from claim construction to the obviousness issue, and whether substantial evidence supported the jury's verdict of nonobviousness, the Federal Circuit first recognized that because the scope and content of the prior art were "factual issues to be determined by the jury," the court was required to "review[] these factual determinations, 'whether explicit or implicit within the verdict, for substantial evidence.'" *Id.* at 17a (quoting *LNP Eng'g Plastics, Inc. v. Miller Waste Mills, Inc.*, 275 F.3d 1347, 1353 (Fed. Cir. 2001)).

The court then discussed Medela's position that the prior art—specifically, Chariker-Jeter, Davydov, Svedman, and Johnson—disclosed "treating wounds with negative pressure" (App. 16a-17a) and identified the substantial evidence that KCI had presented to show that none of the prior art Medela relied on disclosed treating wounds with negative pressure in the manner of the claimed invention (*id.* at 17a-19a). Thus, the court concluded that "KCI addressed each of Defendants' prior art references and provided the jury with a basis for determining that they did not teach or suggest 'treating a wound with negative pressure,' a limitation found in every asserted claim." *Id.* at 19a.

The Federal Circuit also addressed Medela's argument that the district court erred by failing to conduct its own obviousness analysis. But the court noted that Medela's "obviousness argument at trial relied heavily on the prior art references, the scope and content of which are factual questions to be

determined by the jury." *Id.* at 20a. Then, the court recognized that "KCI presented substantial evidence to support its interpretation of the references," and that its obligation under Fifth Circuit case law was to view "the evidence, as well as all reasonable inferences from it," "in the light most favorable to the verdict." *Id.* (citing *Arsement v. Spinnaker Exploration Co.*, 400 F.3d 238, 249 (5th Cir. 2005)). Thus, the Federal Circuit held that it "must assume" that the jury resolved this factual dispute in KCI's favor and concluded that the prior art did not disclose the "treating a wound with negative pressure" limitation. *Id.*

D. Post-Trial PTO Proceedings Regarding the Patents-in-Suit

In its reply brief in the Federal Circuit, Medela stated that it was "noteworthy" that the patents-in-suit "now stand rejected in a reexamination proceeding based upon the Svedman Article." Reply Br. of Appellants, Medela AG and Medela, Inc. ("Medela CAFC Reply Br.") 33 n.6. Subsequently, however, the PTO issued a notice of intent to issue a reexamination certificate for the two patents-in-suit. Following the reexamination proceedings, twelve of the sixteen asserted claims of one asserted patent (U.S. Patent No. 5,636,643) remained unchanged[5] and all twenty-one of the

[5] During the reexaminations, the patentee (Wake Forest University Health Sciences) amended claim 38 of this patent and canceled claims 13-15.

asserted claims of the other asserted patent (U.S. Patent No. 5,645,081) remained unchanged.

III. ARGUMENT

A. Medela Never Objected to the Jury's Role in the District Court

While Medela challenges the Federal Circuit's decision to apply the substantial-evidence test to the jury's verdict of nonobviousness, asserting that it was entitled to an "independent judicial" determination of the issue, Medela has no grounds for complaint. The manner in which the jury's verdict was reviewed—indeed, in which it *had to be reviewed*—was the direct consequence of Medela's own decisions, including its decisions (1) to stipulate to the district court's instructions on obviousness, (2) to provide the jury with a general verdict form in which the jury could answer only "yes" or "no" on the obviousness issue, and (3) not to seek special interrogatories on the factual issues underlying obviousness. Given its *consent* to the procedures followed in the district court, Medela cannot now complain that because the jury answered only "no" on the obviousness issue, the Federal Circuit had to presume that the jury resolved the facts underlying the obviousness issue in KCI's favor. Medela is a sophisticated litigant that was represented by highly qualified counsel. Medela therefore understood the consequences of providing a general verdict form to the jury.

Indeed, for years, the Federal Circuit has strongly encouraged the use of special interrogatories to facilitate review of the jury's factual findings. In *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888 (Fed. Cir. 1984), for example, the jury returned a general verdict (with no objection from the parties) that the claims at issue were valid. As a result, the court noted that "the law presumes the existence of findings necessary to support the verdict the jury reached" (*id.* at 893), and it proceeded to determine whether substantial evidence supported the jury's verdict (*id.* at 893-94). But the Federal Circuit expressly stated that it would have *preferred* that the parties use special interrogatories:

> To facilitate review on a motion for JNOV and on appeal, it is preferred that a jury be provided with special interrogatories designed to reveal more clearly the findings it made.

Id. at 893; *see also* Br. for Apple, Inc., et al., as Amici Curiae Supporting Pet'rs 10-11 (discussing the Federal Circuit's preference for special interrogatories).

And in *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339 (Fed. Cir. 2001), the Federal Circuit noted that the parties' failure to use special interrogatories in the context of determining obviousness made it impossible for the court to determine which specific pieces of evidence the jury relied on in reaching its decision. *Id.* at 1356. Nonetheless, the court held

that the parties were free to use a general verdict if that is what they desired:

> Our law does not compel the use of special verdicts in these cases, and so long as the parties are content to give the jury unfettered room to operate on dispositive factual issues within the scope of a general verdict request, we must be mindful of our role as an appellate court and respect the verdict reached, notwithstanding what may seem to some to be an invention of little novelty.

Id.

Other circuits take a similar approach to litigants who consented to the jury being asked to render a general verdict regarding an issue that is ultimately one of law but has underlying factual issues. For example, *Kerman v. City of New York*, 374 F.3d 93 (2d Cir. 2004), involved the affirmative defense of qualified immunity, which, like obviousness, is a mixed question of law and fact. *Id.* at 109. The court held that, typically, the defendant must request special interrogatories on the key issues of fact, and the court must then decide the ultimate question of law. *Id.* at 119. But because the defendant failed to ask for specific interrogatories, the court held the defense was "effectively waived" because the court could not substitute its factual findings for the jury's. *Id.* at 118. As the court concluded, "it was incumbent on

[defendant] to request that the jury be asked the pertinent question. Not having made such a request, [defendant] was not entitled to have the court, in lieu of the jury, make the finding." *Id.* at 120.

B. The Federal Circuit Properly Reviews Jury Verdicts on Obviousness, and Did So Here

Medela claims that "Federal Circuit precedent broadly and improperly abrogates any right to independent judicial, as distinct from lay jury, determination" of obviousness. Pet. 9. But Federal Circuit precedent has long held that while the jury's underlying factual findings are given due deference, the ultimate question of obviousness is a question of law for the court to decide de novo—i.e., independently. *See, e.g., Jurgens v. McKasy*, 927 F.2d 1552, 1557 (Fed. Cir. 1991) (explaining this two-part appellate review for issues of law, like obviousness, that are submitted to the jury upon disputed facts).

Moreover, the Federal Circuit's cases indicate that, in practice, the court has not abdicated its responsibility to determine the law, and that it has independently reviewed jury verdicts of nonobviousness—and overturned them where appropriate. Looking at Federal Circuit decisions post-dating this Court's decision in *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), for example, shows that in the following cases, the jury's nonobviousness verdict was reversed:

- *PharmaStem Therapeutics, Inc. v. ViaCell, Inc.*, 491 F.3d 1342 (Fed. Cir. 2007). In this case, the Federal Circuit began its review of the jury's obviousness verdict by noting that "[o]bviousness is a legal conclusion that we review de novo." *Id.* at 1359. The court also recognized that "[u]nderpinning that legal issue are factual questions relating to the scope and content of the prior art, the differences between the prior art and the claimed invention, the level of ordinary skill in the art, and any relevant secondary considerations, such as commercial success, long-felt need, and the failure of others." *Id.* Thus, the Federal Circuit stated that "in reviewing the denial of the JMOL motion on the issue of obviousness, we examine the evidence in the light most favorable to the verdict and determine whether a reasonable jury could have found all the facts necessary to support the verdict of nonobviousness, i.e., whether substantial evidence supports the verdict." *Id.* at 1360. The court then provided a multi-page analysis of both the prior art and the testimony presented at trial, including evidence of "secondary considerations," and reversed, concluding that a reasonable jury could not have found the invention nonobvious. *Id.* at 1360-67.

- *Agrizap, Inc. v. Woodstream Corp.*, 520 F.3d 1337 (Fed. Cir. 2008). Here, the jury returned a general verdict that the claims were not obvious and the district court denied the defendant's JMOL motion. In reviewing the judgment, the Federal Circuit noted the jury's role as fact finder and the "high level of deference" that it should thus be

accorded. *Id.* at 1342-43. Further, although the Federal Circuit presumed that all factual disputes were resolved in the patentee's favor, it recognized that it was its duty "to ensure that the law has been correctly applied to the facts." *Id.* at 1343. In other words, the court conducted an independent, de novo review of the legal aspects of the jury's obviousness verdict, deferring only to the jury's presumed factual findings. The court then found the defendant's obviousness case "overwhelming" and reversed the district court's denial of the defendant's motion for JMOL on obviousness. *Id.* at 1344.

- *Boston Scientific Scimed, Inc. v. Cordis Corp.*, 554 F.3d 982 (Fed. Cir. 2009), *petition for cert. dismissed*, No. 09-103, 2009 U.S. LEXIS 7156 (Oct. 2, 2009). In this case, the Federal Circuit reversed the denial of the alleged infringer's JMOL motion on obviousness, stating that "[w]hen we consider that, even in light of a jury's findings of fact, the references demonstrate an invention to have been obvious, we may reverse its obviousness determination." *Id.* at 990.

In short, it is clear that the Federal Circuit has not just *said* that obviousness is an issue of law. In practice, the court has shown that it is committed to conducting an independent review of jury verdicts concerning obviousness and applying the law to the facts either expressly or implicitly found by the jury.

Moreover, the present case reflects just this type of thorough review. Here, the Federal Circuit conducted a thoughtful, independent review of the

evidence that KCI relied on as supporting the jury's verdict. *See supra* pp. 9-12. Indeed, as part of this process, the Federal Circuit thoroughly examined whether the prior art taught "treating a wound with negative pressure," looking at each of the prior-art techniques Medela relied on. *See supra* p. 11.

In sum, the procedure the Federal Circuit followed here in presuming that the jury's factual findings were in KCI's favor was not a consequence of an abdication of its (or the district court's) role in determining the law. It was the procedure this Court's precedent *required* the Federal Circuit to follow under the circumstances of the case. *See, e.g.*, *Reeves v. Sanderson Plumbing Prods., Inc.*, 530 U.S. 133, 150 (2000) (stating that in considering JMOL motions, "the court must draw all reasonable inferences in favor of the nonmoving party"). Medela could have avoided the need to have the Federal Circuit presume the jury's factual findings simply by asking for special interrogatories on the facts underlying the obviousness issue, as the Federal Circuit has expressly encouraged.

C. The Federal Circuit Recognized the Proper Roles of the Jury (Finding the Facts) and the Court (Determining the Law)

1. The "Circuit Split" Is, At Most, Wholly Theoretical

In alleging a "circuit split" on the jury's role in determining obviousness (Pet. 11-17), Medela relies

on two en banc decisions of other circuits that were decided before the Federal Circuit was established to provide nationwide uniformity in patent law. *See, e.g., Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 162 (1989) ("Congress conferred exclusive jurisdiction of all patent appeals on the Court of Appeals for the Federal Circuit, in order to 'provide nationwide uniformity in patent law.'"). But neither of the cases Medela relies on conflicts in any *relevant* way with the Federal Circuit's decision below.

Medela's first "circuit split" case is *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647 (9th Cir. 1982) (en banc) (per curiam). Pet. 11-12. There is no question that, as Medela asserts (*id.* at 11), one aspect of *Sarkisian*—that the jury's role in determining obviousness should be limited to providing (at most) a "nonbinding advisory opinion" (688 F.2d at 651)—has been rejected by the Federal Circuit. *See Perkin-Elmer*, 732 F.2d at 895 n.5. But this difference between the approaches of the two circuits is of absolutely no importance here, and should not affect the decision whether to grant certiorari, since in this case, Medela never asked for an advisory verdict or objected in any way to the issue of obviousness being given to the jury without restrictions. *See supra* pp. 7-8. Indeed, in the Federal Circuit, Medela admitted that it was *not* erroneous to submit the ultimate question of obviousness to the jury. Medela CAFC Reply Br. 3-4 (stating that whether the obviousness question was properly given to the jury was "not the error that

Medela raises," and that the claimed error was that "the District Court erred in failing to engage in any obviousness analysis following the jury's verdict"); App. 19a ("Defendants do not argue that submitting the question of obviousness to the jury is error.").

Further, Medela is wrong in asserting that in *Perkin-Elmer*, the Federal Circuit "rejected the Ninth Circuit's view that the courts must determine nonobviousness independently of the jury's verdict." Pet. 11 (internal quotation marks omitted). On the contrary, the *Perkin-Elmer* court recognized that courts should determine obviousness "independently" of the jury, but held that this did not mean that the jury's verdict could be ignored. In affirming the district court's denial of the alleged infringer's JNOV motion, the Federal Circuit said the following:

> The [trial] court did not, however, appear to interpret the indication in [*Sarkisian*] that it should determine nonobviousness "independently" of the jury's verdict as requiring it to totally ignore the rules applicable to jury trials in non-patent cases, or to proceed as though the jury had never been impanelled, had never been instructed on the issue, had never considered the issue, and had never rendered a verdict on its conclusion.

Perkin-Elmer, 732 F.2d at 895. Thus, the Federal Circuit noted that the trial court had "proceeded in a

manner similar to that involved in deciding a motion JNOV and used the jury's presumed findings supported by substantial evidence." *Id.* And the Federal Circuit concluded that the trial court had "in fact answer[ed] the appropriate question: can the jury's presumed findings support [the] conclusion of nonobviousness encompassed in the jury's verdict of validity?" *Id.*

In sum, in *Perkin-Elmer* (as well as in this case), the Federal Circuit viewed the ultimate issue of obviousness as a legal conclusion (as all courts have), and it also recognized its obligation (as all courts have) to give effect to the jury's factual findings. The Federal Circuit in *Perkin-Elmer* differed with the Ninth Circuit in *Sarkisian* on the question of whether the jury should ever render anything more than a purely advisory verdict on the ultimate issue of obviousness, but that difference has no relevance here, since Medela *consented* to the jury rendering the obviousness verdict.

Medela's second "circuit split" case is *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324 (7th Cir. 1983) (en banc). Pet. 13-14. Medela argues that *Roberts* rejected the Federal Circuit's approach of "requiring a court to hypothesize" the jury's factual findings (*id.* at 13), but what the Seventh Circuit objected to in *Roberts*—where the alleged infringer *had* objected to giving the obviousness issue to the jury (723 F.2d at 1339)—was *not* the need to presume the jury's factual findings from its verdict, but the cursory nature of the instructions the jury

had been given. As the *Roberts* court pointed out, the instructions given there "merely identified the *Graham* underlying factual inquiries and instructed the jury to 'consider the evidence' presented by the parties with respect to them." *Id.* Under those circumstances, the court recognized that the jury was being asked, improperly, to "be the final arbiter of the legal issue of patent validity." *Id.* at 1343.

Indeed, the *Roberts* decision repeatedly emphasized that it is the court's role to determine the law and the jury's role to determine the facts. *See, e.g., id.* at 1341 ("[Q]uestions of law are for the court and questions of fact are for the jury."); *id.* at 1343 ("We do not intend as a court to make a jury's factual decisions."). The court thus held that as long as the court's and jury's separate roles are recognized through proper instructions, asking the jury to return a general verdict on obviousness is perfectly appropriate, since the court can then *presume* that the jury resolved disputed factual matters in the prevailing party's favor. *Id.* at 1341 ("On appeal [from a general verdict on obviousness], the reviewing court will presume that 'the disputed matters of fact have been resolved favorably to the prevailing party in accordance with the trial judge's instructions.'" (quoting *Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225, 228 (7th Cir. 1972))). The problem the court had in *Roberts*, therefore, was not that it objected to the concept of having to presume the jury's factual findings, but that the trial court's cursory instructions "preclude[d it] from confidently presuming that [the] factual

disputes [underlying obviousness] were resolved in favor of Roberts." *Roberts*, 723 F.2d at 1343.

Moreover, in recognizing the jury's role to find the facts and the court's role to determine the law, the *Roberts* court expressly described the court's role as being to conduct an "independent" review of the obviousness issue. It is just that the *Roberts* court recognized (as the Federal Circuit did in this case) that its role, while independent, was circumscribed by the fact-law distinction and the Federal Rules of Civil Procedure:

> When made in a bench trial, the *Graham* factual determinations are reviewed under the clearly erroneous standard of Rule 52(a), Federal Rules of Civil Procedure. When these factual determinations have been made by a jury, our review is limited, assuming the instructions are not an issue, to ascertaining whether the denial of a motion for a new trial or a motion for a judgment notwithstanding the verdict was an abuse of discretion. *An appellate court's independent review of the trial judge's conclusion of law is predicated upon the factual determinations made in the district court.*

Roberts, 723 F.2d at 1335 (emphasis added); *see also id.* at 1342 n.24 (noting that in *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763 (5th Cir. 1980), the

Fifth Circuit had approved a general verdict on obviousness, stating that "[t]he court of appeals' *independent review* of the record disclosed substantial evidence in support of the jury's presumed findings of fact [on the obviousness issue]" (emphasis added)).

In sum, the Seventh Circuit's approach to obviousness in *Roberts* is fully consistent with the Federal Circuit's approach. As is true of the Federal Circuit, the Seventh Circuit in *Roberts* recognized the role of juries (finding the facts) and courts (determining the law), and approved asking the jury to return a general verdict on obviousness on proper instructions. And to the extent that the Seventh Circuit may have spoken in greater detail regarding the specific instructions that may be required, that difference is irrelevant in the present case since, again, Medela *consented to* the instructions on obviousness that the jury received in this case.

Medela is also incorrect in asserting that *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982), reveals either an "intra-circuit split" in the Fifth Circuit or that the Fifth Circuit "has moved into alignment with the circuits opposing the Federal Circuit position." Pet. 15-16 (quoting *Baumstimler*, 677 F.2d at 1072). In *Baumstimler*, the Fifth Circuit vacated the district court's judgment based on faulty jury instructions concerning the burden of proof for invalidity. 677 F.2d at 1063. Then, the court decided to "offer some comments to facilitate retrial." *Id.* at 1063 n.1.

While highly critical of the verdict form used in that case—which did not even require the jury to make a specific finding of validity (*id.* at 1065, 1071)—the court did not broadly forbid general verdicts in the obviousness context or say that if a general verdict was used, a jury's presumed factual findings should be ignored. To be sure, the *Baumstimler* court expressed a strong preference for special interrogatories (*id.* at 1071-72), but so has the Federal Circuit (*see supra* p. 14). And while the *Baumstimler* court suggested that it would be less tolerant of general verdicts in the future, saying that a "failure to utilize [special interrogatories] in a patent case places a heavy burden of convincing the reviewing court that the trial judge did not abuse his discretion" (677 F.2d at 1071-72), it said nothing about what it would do if the parties voluntarily agreed to submit the issue of obviousness to a jury.

In sum, none of the cases Medela relies on conflicts with the Federal Circuit's decision below *in any relevant way.*

2. The Federal Circuit's Approach Was Consistent with This Court's Precedent

Medela argues that Federal Circuit precedent conflicts with this Court's precedent on obviousness. Pet. 17-19. But Medela's argument is based on the statement in *Graham* that "the ultimate question of patent validity, is one of law" (*id.* at 17 (citing *Graham*, 393 U.S. at 17)), and no one—including the

Federal Circuit—has ever disputed that. *See, e.g.*, *PharmaStem*, 491 F.3d at 1359 ("Obviousness is a legal conclusion that we review de novo."). Further, that this Court's *KSR* decision makes "no mention whatsoever of juries conducting the analysis" (Pet. 17) is wholly irrelevant. *KSR* was determined on summary judgment where no jury was involved. *KSR*, 550 U.S. at 412. In fact, *none* of the Supreme Court case law cited by Medela (Pet. 2-3)[6] involved an appeal following a jury trial. But beyond that, the jury in the present case did not "conduct the analysis" of obviousness in the sense Medela implies. The jury here (following consented-to instructions) *found the facts underlying obviousness* and then reached a verdict on obviousness that, following the district court's instructions, flowed from those facts. And the district court then performed its role (as the Federal Circuit later did on appeal), deciding whether the jury's decision was legally correct while presuming (since it had no other option) that the jury's factual findings were in KCI's favor as the prevailing party.

Finally, Medela's complaint that the instructions on obviousness were deficient because they were only seven pages long, while one casebook

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[6] *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273 (1976) (no reference to jury trial); *Dann v. Johnston*, 425 U.S. 219 (1976) (appeal from ex parte prosecution); *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57 (1969) (no reference to jury trial); *United States v. Adams*, 383 U.S. 39 (1966) (appeal from Court of Claims).

"devotes over 160 pages to the exposition of obviousness law" and two other legal sources spend, respectively, 25-plus and 40-plus pages on the issue (Pet. 18-19), strains credulity. The *length* of the instructions is not the issue. Medela points to no *error* in the instructions, and in any event, the fact remains that Medela *stipulated* to them. *See supra* pp. 7-8.

D. Medela's Argument that the Jury Should Have *No* Role in Deciding Obviousness Goes Too Far

Medela concludes its brief with an outright attack on the jury having *any* involvement in the determination of obviousness. Pet. 19-30. But this request contradicts a core principle of our judicial system—that it is the jury's province to determine the credibility of trial witnesses and make factual findings, not the court's. Medela's request should be rejected out of hand.

Medela begins its argument by discussing cases that deal with administrative orders and arguing that because the PTO is an administrative agency and a patent is an administrative order, any fact-finding required in determining obviousness should be performed by a judge, not a jury. *Id.* at 19-22. But whether or not certain challenges to administrative orders may—under the particular circumstances of those cases—involve factual issues that a judge resolves is wholly beside the point.

Beginning at least as early as in *Hotchkiss v. Greenwood*, 52 U.S. (11 How.) 248 (1851), this Court has approved giving the issue of obviousness to the jury on proper instructions. *Id.* at 267. And in *Graham*, where this Court dictated that there are "basic factual inquiries" underlying the ultimate legal determination of obviousness (*see* 383 U.S. at 17), the clear implication was that if a jury was involved in the case, it would decide the factual issues. Moreover, *every* court that has considered the issue—including Medela's "circuit split" cases, *Sarkisian* and *Roberts*—has concluded that the facts underlying obviousness are to be decided by the jury. *See Sarkisian*, 688 F.2d at 650 (finding that the *Graham* factors are "factual determinations . . . made by the fact finder, preferably by detailed special interrogatories in jury trials"); *Roberts*, 723 F.2d at 1333 ("[W]here material factual disputes exist . . . , issues for jury determination, if a jury is to be the fact-finder, are presented."). Indeed, Medela does not argue otherwise.

Further, the Federal Circuit's treatment of obviousness is consistent with this Court's treatment of other patent-law issues that involve mixed questions of fact and law. In *Tucker v. Spalding*, 80 U.S. (13 Wall.) 453 (1872), for example, this Court held that the question of novelty, being a "mixed question of law and fact," must be given to the jury on proper instructions:

> [T]hough the principles by which the question must be decided may be very

> largely propositions of law, it still remains the essential nature of the jury trial that while the court may on this mixed question of law and fact, lay down to the jury the law which should govern them, so as to guide them to truth, and guard them against error, and may, if they disregard instructions, set aside their verdict, the ultimate response to the question must come from the jury.

Id. at 455. *See also Hogg v. Emerson*, 52 U.S. (11 How.) 587, 607 (1850) (stating that because the question of whether the patent-in-suit's drawings were corrected within a reasonable time was "a point in part of law and in part of fact," the issue "was properly submitted to the jury, and their finding must stand, unless it is shown, as has not been done, that illegal instructions were given to them concerning it, or that proper legal directions were omitted").

The entitlement to having a jury decide mixed questions of fact and law is equally true in areas outside of patent law. *See, e.g., McDermott Int'l, Inc. v. Wilander*, 498 U.S. 337, 356 (1991) (holding that the question of who is a "seaman" under the Jones Act is "better characterized as a mixed question of law and fact," that "[t]he jury finds the facts and, in these cases, applies the legal standard," and that so long as "reasonable persons, applying the proper legal standard, could differ," the issue of

seaman status "is a question for the jury"); *Manchester v. Ericsson*, 105 U.S. 347, 350 (1881) (holding that the question of whether the city of Manchester had "assumed charge of the place" where an accident occurred "was a mixed question of law and fact, proper for the jury, aided by the court"); *Republican River Bridge Co. v. Kan. Pac. Ry. Co.*, 92 U.S. 315, 318 (1875) (holding that the ownership of real estate "must from its very nature be a mixed question of law and fact, which would be concluded by the verdict of a jury"); *Cooley v. O'Connor*, 79 U.S. (12 Wall.) 391, 400 (1870) ("Whether the demands of the statute respecting notice of sale had been complied with was a mixed question of law and of fact, and it should have been submitted to the jury."); *Chesapeake Ins. Co. v. Stark*, 10 U.S. (6 Cranch) 268, 273 (1810) (holding that the issue of whether an abandonment was made in reasonable time "remains a question, compounded of fact and law, which must be found by a jury, under the direction of the court").

Moreover, while Medela cites an article broadly questioning "the ability of juries to decide complex patent cases rationally" (Pet. 26), that has never been the view of this Court. As is seen from the cases discussed above—including especially *Hotchkiss* (regarding obviousness) and *Tucker* (regarding novelty)—this Court has never hesitated to allow juries in patent cases to resolve issues that are unquestionably complex. *See also Mach. Co. v. Murphy*, 97 U.S. 120, 125 (1877) (holding, on the issue of infringement under the doctrine of

equivalents, that "in determining the question of infringement, the court or jury, as the case may be, . . . are to look at the machines or their several devices or elements in the light of what they do, or what office or function they perform, and how they perform it, and to find that one thing is substantially the same as another, if it performs substantially the same function in substantially the same way to obtain the same result").

Also, patent law is hardly the only area of the law that involves complex issues. And while some courts have recognized the *theoretical* possibility of a complexity exception to the right to a jury trial, to KCI's knowledge, neither this Court nor any court of appeals has ever held that the right to a jury should be abrogated in a given case because of the case's complexity—whether in the context of patent law, securities law, antitrust law, or any other area of the law that may involve difficult issues. In *Davis & Cox v. Summa Corp.*, 751 F.2d 1507 (9th Cir. 1985), for example, the court held that it was error to refuse a jury demand because of the complexity of an issue:

> [T]here is no complexity exception to the Seventh Amendment right to jury trial in civil cases. . . . And we do not believe any case is so overwhelmingly complex that it is beyond the abilities of a jury.

Id. at 1516 (quoting *In re U.S. Fin. Sec. Litig.*, 609 F.2d 411, 432 (9th Cir. 1979)). *See also United*

States v. Torniero, 735 F.2d 725, 734 (2d Cir. 1984) ("The framers of the Bill of Rights expected that juries would be capable of resolving disputed issues of fact in the federal courts. Even in civil litigation, where non-perspicuous issues and abstruse evidence proliferate, we have never acknowledged a 'complexity exception' to the right to a jury trial.") (citation omitted); *In re Japanese Elec. Prods. Antitrust Litig.*, 631 F.2d 1069, 1088 (3d Cir. 1980) (recognizing the theoretical possibility that a suit may be so complex that trial by jury might be denied, but holding that "[t]he complexity of a suit must be so great that it renders the suit beyond the ability of a jury to decide by rational means").

Similarly irrelevant is Medela's complaint (based on the same article) that juries have been used in patent cases more frequently in recent years than in the past (Pet. 26). The preference of some parties—whether patentees or alleged infringers, and whether for or against juries—is simply irrelevant to the determination of the proper *constitutional* role of the jury in patent cases.

Medela also cites this Court's grant of certiorari in *American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995), as allegedly "the best gauge of importance" to the issue presented in this case. Pet. 23. But the question in *American Airlines* was whether there was a right to a jury trial in a declaratory-judgment action where the claimant did not seek legal relief. That question is hardly similar to the question of the jury's proper role in the

determination of an issue, such as obviousness, that is admitted to be a legal issue with underlying factual issues. Moreover, while Medela quotes Judge Nies's dissent from the denial of rehearing en banc in *Lockwood* (Pet. 23), she would not have sympathized with Medela in this case. Despite her dislike of "black box" jury verdicts, Judge Nies also stated that "[i]f both parties agree to that procedure, so be it." *In re Lockwood*, 50 F.3d 966, 990 (Fed. Cir. 1995) (Nies, J., dissenting).

In fact, while Medela ignores the effect of its consent to the procedures followed in the district court, it is hard to contemplate why Medela should be excused from the consequences of its decision. If the jury had found for Medela on the obviousness issue, Medela would have been perfectly content with the verdict and would never have argued that the court was required to ignore the verdict and decide obviousness on its own. In short, there is no reason for this Court to consider Medela's after-the-fact complaints about a procedure that it fully consented to at the time.

CONCLUSION

For the foregoing reasons, Medela's petition for a writ of certiorari should be denied.

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IN THE

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MEDELA AG and MEDELA, INC.,

Petitioners,

—against—

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., and WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Respondents.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF

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October 27, 2009

CORPORATE DISCLOSURE STATEMENT

Petitioners' corporate disclosure statement was set forth at page ii of their Petition for a Writ of Certiorai, and there are no amendments to that statement.

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William F. Lee et al., *Reflections on the Ongoing Role of Juries in Determining Obviousness in Patent Cases After the Supreme Court's Decision in KSR*, 76 Pat. Trademark & Copyright J. (BNA) 1 (2008) 6

Six major U.S. corporations (Apple, Inc., Cisco Systems Inc., Google, Inc., Microsoft Corp., Symantec Corp., and Yahoo!, Inc.) have urged this Court to grant certiorari in this case, because [i] "general jury verdicts regarding obviousness, such as that employed in the present case, have become commonplace, if not standard practice"; [ii] "such general verdicts on the ultimate legal question of obviousness inadvisably sideline judges from fulfilling their critical responsibility to decide this important legal issue"; and [iii] "misapplication of this Court's obviousness jurisprudence has created practical litigation problems that are so chronic that the issue is particularly worthy of the close attention of this Court." Brief for Apple et al. ["Apple Br."] at 2, 4.

In another brief authored by former Solicitor General Theodore Olson and filed on behalf of Intel Corporation, SAP America, Inc., and Shoretel, Inc., the amici similarly urge this Court to grant certiorari in this case, because: "The Federal Circuit's failure to require an independent judicial (rather than lay jury) determination of obviousness [i] presents an issue of substantial and recurring practical importance," [ii] "provides patent holders possessing invalid patents with a tactical advantage in bringing an infringement suit, [iii] renders patent litigation more costly and uncertain, and [iv] prevents meaningful judicial review." Brief for Intel et al. ["Intel Br."] at 16.

In addition to underscoring the practical importance of the question presented in the Petition, the amici briefs confirm undeniable points that support certiorari in this case, including:

- the clear and acknowledged circuit split between long-standing Federal Circuit precedent and en banc holdings by the Ninth and Seventh Circuits (Pet. at 11-17; Apple Br. at 18-22; Intel Br. at 13-16);
- the conflict between Federal Circuit precedent and this Court's precedent applying 35 U.S.C.

§ 103 including *KSR International Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), wherein this Court stated that analysis of patent validity under § 103 "should be made explicit" so as "[t]o facilitate review," *id.* at 418 (Pet. at 17-19; Apple Br. at 8-9; Intel Br. at 4, 8-13);

- the conflict between Federal Circuit precedent and this Court's precedent prescribing the allocation of decisional power between judge and jury in other areas of law (Pet. at 19-22; Apple Br. at 23 & n.5; Intel Br. at 10-13);
- the practical impediment to meaningful post-trial or appellate review of patent validity issues that Federal Circuit precedent has created (Pet. at 17-18; Apple Br. at 4-6, 16-18; Intel Br. at 4-5, 16-22); and
- the appropriateness of using this case as a vehicle to address the question presented in the Petition (Pet. at 24; Apple Br. at 25; Intel Br. at 22).

Lacking any substantial basis for arguing that the question presented in the Petition does not merit this Court's review, Respondents devote the bulk of their opposition to groundless arguments that Petitioners purportedly are not entitled to raise the question presented in the Petition. Tellingly, however, Respondents do not cite or discuss this Court's precedents defining when an issue is properly presented for this Court's review.

This Court has articulated a clear and crisp test for whether an issue is properly presented for review in this Court: "Any issue 'pressed or passed upon below' by a federal court is subject to this Court's broad discretion over the questions it chooses to take on certiorari." *Verizon Communications Inc. v. FCC*, 535 U.S. 467, 530 (2002) (quoting *United States v. Williams*, 504 U.S. 36, 41 (1992)). As discussed in point 1 below, both of those alternative prongs to that test are satisfied here, as the question presented

in the Petition was both "pressed" in and "passed upon" by the Court of Appeals below.

Further, as discussed in point 2 below, Petitioners most certainly did not "consent" to "giving the issue to the jury." Opp. at i. Respondents never once raised this argument below, and for good reason: Petitioners never agreed to have the jury decide obviousness and unequivocally sought to have the courts below determine the obviousness issue independently.

Respondents' other arguments for evading review in this Court are equally meritless as set forth in points 3-8 below. One of Respondents' arguments – that this case implicates "the proper *constitutional* role of the jury in patent cases" (Opp. at 33; emphasis in original) – at best contributes an additional reason for *granting* certiorari in this case, as this Court is the final arbiter of constitutional issues in our legal system.

1. The Question Presented in the Certiorari Petition Was Pressed and Passed Upon Below.

Petitioners devoted an entire section of their Federal Circuit brief to the argument that: "The District Court Erred in Not Making Its Own Conclusion on Obviousness." Pet. C.A. Br. at 54. Countering that argument, the Respondents relied solely on Federal Circuit precedent to argue that "'the issue of obviousness may be given to the jury with proper instructions'" and that, when the issue is so given to the jury, the "court's review of the verdict" is limited "to ensur[ing] that it was supported by substantial evidence." Resp. C.A. Br. at 65 (quoting and relying on *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 764-65 (Fed. Cir. 1988)).

The majority opinion below expressly addressed Petitioners' "argument . . . that the district court erred by failing to conduct its own obviousness analysis," Pet. App. 19a; *see also id.* at 12a (correctly stating that Petitioners here were "contend[ing] that the district court was required to conduct its own

independent obviousness analysis and erred by simply reviewing the jury's verdict for substantial evidence"). The majority rejected Petitioners' argument on the merits, holding that, because "KCI presented substantial evidence to support its interpretation of the references," the court was required to "assume" that the jury adopted a certain legal rationale and found certain facts (*id. at* 20a), assumptions that did not even pretend to be grounded in any *actual* findings or legal rationale that the jury used or applied. *See id.* at 17a ("This court reviews these factual determinations, whether explicit or *implicit within the verdict*, for substantial evidence") (emphasis added).

In sum, the Federal Circuit in this case engaged in precisely the sort of *non*-independent review that Petitioners objected to below and that Respondents championed below. The court decided the issue, siding with the Respondents' arguments. That ruling plainly engages the relevant circuit split and unequivocally provides the proper procedural foundation for raising the question presented in the Petition.

2. Respondents' "Consent" Argument Was Never Presented Below and Is Baseless.

For the first time in this Court, Respondents assert that Petitioners purportedly "*consented* to giving the issue of obviousness to the jury." Opp. at i (emphasis in original), with the purported result that Petitioners are thereby somehow disabled from raising the question presented in the Petition. Respondents never made this "consent" argument below. Indeed, the word "consent" appears nowhere in the Respondents' brief below, and not surprisingly, also appears nowhere in the Federal Circuit's opinion. Those clear and unequivocal facts are entirely sufficient to reject the notion that some fictitious "consent" could present a procedural problem in this case.

The Respondents' "consent" argument is also baseless. Not once in the entirety of their Opposition

Brief do Respondents cite to any portion of the record to prove that Petitioners gave "consent" to a jury determination of obviousness that would preclude independent judicial determination of that issue. Even under Ninth Circuit precedent, juries may render advisory verdicts on obviousness under Federal Rule of Civil Procedure 39(c)(1).

The relevant issue—the issue on which there is an acknowledged circuit split—is not *whether* a jury may express a lay opinion on the legal question of obviousness, but rather *what effect* such a verdict should have, *i.e.*, whether a jury verdict on the legal question of obviousness is properly held to preclude a court's independent review of that question. That issue was fully presented, joined in argument by both sides below, and decided by the Court of Appeals.

Consistent with its longstanding precedent, the Federal Circuit here held that a jury verdict on the legal question of obviousness operates to preclude independent judicial determination of that issue. The Ninth and Seventh Circuits have held that such a jury verdict has no such preclusive effect. *See* Pet. at 11-14; Apple Br. at 18-22; Intel Br. at 13-16. This issue was both pressed and passed upon below, and is thus properly presented to this Court for review.

3. The Question Presented in the Certiorari Petition Does Not Challenge the Jury Instructions.

Respondents' argument that Petitioners did not "object to the instructions on obviousness," Opp. at 7, is utterly irrelevant, because the question presented for certiorari also does not challenge the jury instructions on obviousness.

Petitioners' discussion of the jury instructions (Pet. at 5-6) was intended to illustrate how legal conclusions of obviousness depend on complex weighing and balancing of multiple interdependent factors, and that jury instructions on obviousness cannot substitute for a law school education in patent law.

The record of this case illustrates the wisdom of the approach of the Ninth and Seventh Circuits, under which a jury's general verdict of obviousness is, at most, advisory.

4. The Federal Circuit's Hortatory "Encouragement" of Factual Interrogatories Does Nothing to Address the Circuit Split

Respondents repeatedly argue that "the Federal Circuit has *encouraged* parties to request the submission of factual interrogatories to the jury precisely to facilitate the review of the verdict." Opp. at 3 (emphasis in original); *see also id.* at 1, 14 & 19. The key words in that passage are "encourage" and "request."

It is true that some Federal Circuit cases have included dicta "counsel[ing] district courts in appeals to us that specific answers from the jury on factual issues are *desirable*," *Structural Rubber Prods. Co. v. Park Rubber Co.*, 749 F.2d 707, 720 (Fed. Cir. 1984) (emphasis added), but under unequivocal and long-standing Federal Circuit precedent, it is entirely proper for a district court to deny such requests. *See, e.g. Shatterproof Glass Corp. v. Libbey-Owens Ford Co.*, 758 F.2d 613, 627 (Fed.Cir. 1985).[1] It is thus simply incorrect to assert, as Respondents do, that "Medela could have avoided the need to have the Federal Circuit presume the jury's factual findings simply by asking for special interrogatories on the facts underlying the obviousness issue, as the Federal Circuit has expressly encouraged." Opp. at 19.

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[1] Any supposed "encouragement" of special interrogatories in patent cases has also been stunningly ineffective, for as amici note (Apple Br. at 4), the pattern jury instructions routinely used in the lower courts show a "clear trend" that "favors a general verdict approach (leading to so-called 'black-box verdicts')." William F. Lee et al., *Reflections on the Ongoing Role of Juries in Determining Obviousness in Patent Cases After the Supreme Court's Decision in KSR*, 76 Pat. Trademark & Copyright J. (BNA) 1, 4 (May 30, 2008).

Furthermore, it was Respondents, not Petitioners, that demanded trial by jury in this case and opposed independent judicial determination of the issue of obviousness. Under Federal Rule of Civil Procedure 49(a)(3), a party seeking to have a jury decide an issue of fact must demand its submission to the jury or be deemed to have waived the right to jury trial on that issue. In these circumstances, Petitioners' right to seek review of the question presented by the Petition can hardly be diminished by reason of the *Respondents'* waiver of their claimed right to trial by jury of facts pertinent to whether subject matter claimed in Respondents' patents was properly deemed "non-obvious subject matter."

5. Respondents Fail to Distinguish the Circuit Split.

Respondents concede that Federal Circuit precedent stands in open conflict with Ninth Circuit precedent. Opp. at 20. The only issue of dispute is the depth of the circuit split.

Respondents assert that Federal Circuit precedent is purportedly "fully consistent" with Seventh Circuit precedent. Opp. at 25. It is not.

As set forth in the Petition (Pet. at 13-15), Seventh Circuit precedent holds that a jury may render a verdict on the legal question of obviousness *only* in circumstances where that legal conclusion *necessarily* follows from *particular* predicate facts and the district court instructs the jury "that it should return one verdict if the facts are found one way and a different verdict if the facts are found otherwise." *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1341 (7th Cir. 1983) (en banc) (quoting *Panther Pumps & Equip. Co v. Hydrocraft, Inc.*, 468 F.2d 225, 228 (7th Cir. 1972)).

As amici note, it is only in an exceedingly unusual case, such as one in which "the only factual dispute is whether or when an article was actually published" (Apple Br. at 16), that a district court will be able to give the type of instruction that, under

Seventh Circuit precedent, will permit a lay jury "to express its opinion on the legal issue." *Roberts*, 723 F.2d at 1342. The theoretical possibility of such cases renders no less real and substantial the conflict between Federal Circuit and Seventh Circuit precedent identified in the Petition (Pet. at 14-15) and amici briefs (Apple Br. at 19-20; Intel Br. at 14).

If Seventh Circuit precedent had been applied in this case, where the jury was tasked with determining both a legal issue (namely, the legal meaning of the patent claim word "wound"; *see* Pet. App. 36a-41a) and multiple different factual issues that bore on the ultimate legal determination of obviousness (*see* Pet. at 5-6), the result clearly would have been reversal, not affirmance; for as the Seventh Circuit held on similar facts: "the trial court could not presume, nor may we, that the facts were found in favor of Roberts merely because the jury ultimately made the legal determination that his patent would not have been obvious." 723 F.2d at 1342.

6. Post-KSR Federal Circuit Decisions Do Not Militate Against Granting Certiorari.

The three post-*KSR* Federal Circuit decisions cited by Respondents demonstrate that, even under the extremely deferential standard of review applied by the Federal Circuit, some jury verdicts cannot withstand scrutiny because no "reasonable jury" could have possibly rejected obviousness defenses on given records. Such decisions hardly inspire confidence in a legal regime that routinely allows juries to render general "black box" verdicts on the legal issue of obviousness.

More importantly, those cases clearly do not show that the Federal Circuit "is committed to conducting an independent review of jury verdicts concerning obviousness." Opp. at 18. Even the Respondents' own description of those cases makes clear that the Federal Circuit is not independently determining obviousness questions but is instead applying the law "to the facts either expressly or implicitly

found by the jury." *Id.* Indeed, in all of the cited cases, the jury made no explicit factual findings and the Federal Circuit was "re-creating facts as they may have been found by the jury." *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1351 (Fed. Cir. 2001). *See* Pet. at 4, 8-9. That is precisely the sort of procedure expressly condemned by en banc decisions of the Ninth and Seventh Circuit. *See* Pet. at 12-14.

7. The Court's Prior Grant of Certiorari in Lockwood Supports Granting Certiorari Here.

As noted in the Petition (Pet. at 22-24), the question presented in *American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995), and the question presented in this case both concern the allocation of power between judge and jury on patent validity issues. Indeed, in arguing in favor of en banc review in *Lockwood*, Judge Nies's dissent expressly relied on precisely the same circuit split that Petitioners have asserted here. Thus, the objective facts demonstrate that, contrary to Respondents' arguments, the questions presented in the two cases are quite similar.

It is also true that the question presented in *Lockwood* was different: Because it was limited to the declaratory judgment posture, the question there was narrower and much less frequently litigated, and unlike in this case, the question in *Lockwood* arose in an interlocutory posture in which the question was always susceptible to being rendered moot. Still, this Court granted certiorari. Thus, while Respondents are correct that the two cases are different, all of the distinctions between *Lockwood* and this case make this case appear more worthy of certiorari than *Lockwood* was.

8. Respondents' Constitutional and Other Merits Arguments Provide Additional Support for Certiorari.

Respondents also raise a number of arguments on the merits, but none of these detract from the case for granting certiorari. Several highlight the need for certiorari.

For example, Respondents assert that this case involves "the determination of the proper *constitutional* role of the jury in patent cases." Resp. Br. at 33 (emphasis in original). But Respondents' constitutional argument merely makes review by this Court all the more necessary because, unlike purely statutory issues, Congress cannot remedy a misinterpretation of the Constitution.

Second, Respondents do not even purport to distinguish this Court's clear holding that "the constitutional right to jury trial does not include the right to have a jury pass on the validity of an administrative order." *Cox v. United States*, 332 U.S. 442, 453 (1947). Rather, Respondents merely argue that applying such a generally applicable rule of administrative law "goes too far." Opp. at 28. The absence of any reasoning to distinguish ordinary principles of administrative law provides yet another indication that certiorari is needed here.

Finally, Respondents emphasize that "*none*" of this Court's precedents on the obviousness doctrine of § 103 have directly addressed the allocation of decisional power between the judge and the jury. Opp. at 27 & n.6. But that very lack of explicit guidance, coupled with the circuit split, the importance of the issue, the scholarly and governmental attention to the matter, and this Court's own statements suggesting the importance of explicit analysis, demonstrates the need for certiorari.

CONCLUSION

A writ of certiorari should issue to review the judgment of the Federal Circuit in this case.

Respectfully submitted,

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IN THE

Supreme Court of the United States

MEDELA AG AND MEDELA, INC.,
Petitioners,

v.

KINETIC CONCEPTS, INC.,
KCI LICENSING, INC., KCI USA, INC.,
AND WAKE FOREST UNIVERSITY HEALTH SCIENCES,
Respondents.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the Federal Circuit

BRIEF FOR APPLE, INC., CISCO SYSTEMS, INC., GOOGLE, INC., MICROSOFT CORP., SYMANTEC CORP., AND YAHOO!, INC. AS *AMICI CURIAE* SUPPORTING PETITIONERS

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Apple, Inc., Cisco Systems, Inc., Google, Inc., Microsoft Corp., Symantec Corp., and Yahoo!, Inc. (*Amici*) are high-technology leaders, whose innovative products and services have gained worldwide recognition. Their research and development investments have led to important patents protecting the technology at the heart of their products and services.

Because patent rights are important to *Amici*, they appreciate the importance of a healthy patent system. At the same time, their products and services are the targets of frequent infringement assertions. Based on *Amici's* balance of interests as well as their extensive experience with the patent litigation system, they provide the Court with their views on the issues before this Court, including centrally the proper role of the judiciary in determining whether a patent is "non-obvious" as required by 35 U.S.C. § 103. *Amici* are hopeful that the views expressed in this brief will assist the Court in addressing the important question presented by the petition.[1]

INTRODUCTORY STATEMENT

Determining when a claimed invention is "obvious" is a difficult task that can be vexing even

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[1] *Amici* provided counsel of record with notice of their intent to file this brief more than ten days prior to the due date, as required by Supreme Court Rule 37.2(a). All parties have consented to the filing of this brief. In accordance with Supreme Court Rule 37.6, *Amici* state that this brief was not authored, in whole or in part, by counsel to a party, and that no monetary contribution to the preparation or submission of this brief was made by any person or entity other than *Amici* or its counsel.

for the most diligent and conscientious decision-maker. This legal problem presents such a challenge because it can involve, among other things, the complicated consideration of when one entity should be given exclusive rights to an incrementally new technique. Standing alone, this issue implicates thorny line-drawing problems for judges, as this Court documented recently in *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007).

But it does *not* stand alone. The inherent challenges in deciding what is legally "obvious" are exacerbated by the Federal Circuit authority that encourages courts to delegate their responsibility for the obviousness determination to jurors. In practice, this results in both district courts and the Federal Circuit failing to perform express obviousness analyses themselves, even though this Court has repeatedly held it is an issue of law that should be analyzed explicitly. This misapplication of this Court's obviousness jurisprudence has created practical litigation problems that are so chronic that the issue is particularly worthy of the close attention of this Court.

Indeed, a question remarkably similar to the one presented here was of sufficient interest to this Court for it to have granted certiorari in the recent past. *See American Airlines, Inc. v. Lockwood*, 515 U.S. 1121 (1995) (No. 94-1660) (presenting the question of the respective roles of the judge and juries relating to patent invalidity). Unfortunately, the proper role of a judge in deciding issues of obviousness was not clarified in *Lockwood* because the private parties mooted the issue before this Court could resolve the case. This case presents a

fresh opportunity for this Court to address this issue, which has only become more important as an increasing number of patent cases are tried to juries.

The question now presented for review is whether judges can and should conduct an independent determination of obviousness, even when the issue has been submitted to a jury. *Amici* respectfully urge this Court to grant the petition to consider the proper role of courts in deciding obviousness when factual questions are present. Because of the character of the patent right and to address the awkward split of responsibility between the court and the jury that currently plays out in district courts every day, judges should be expressly and unambiguously given the authority to fulfill their responsibility to address the legal question of obviousness based on a plenary evaluation of the record.

SUMMARY OF ARGUMENT

This Court should grant the petition so as to reaffirm its prior rulings that judges—not juries—bear the responsibility, and have the authority, to analyze the legal question of whether an asserted patent meets the nonobviousness requirement of 35 U.S.C. § 103(a). This rule is not being followed. Clarifying the paramount role of the judiciary in resolving the legal question of obviousness would solve the myriad practical problems currently experienced on a daily basis throughout the national jurisdiction of the Federal Circuit.

In *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1 (1966), this Court continued the centuries-old quest for a "more practical test" for obviousness. *Id.*

at 17. The Court confirmed that the obviousness determination is a question of law for the court based on underlying factual questions, including the scope and content of the prior art, differences between the prior art and the claims at issues, and the level of ordinary skill in the pertinent art. *Id.*

As the *Graham* framework is currently implemented in the lower courts, however, the entire issue of obviousness is usually tried to a jury upon a general verdict. The potential alternative under current Federal Circuit law is to ask the jury to answer, through an essay or otherwise, the often dense factual questions identified in *Graham* via special interrogatory or special verdict. But given the breadth and complexity of those factual questions in many cases (albeit not always), this can be far too cumbersome and impractical. While some experimentation has been attempted, little headway has been made in preserving the role of the courts in deciding obviousness where underlying factual questions exist.

For such reasons, general jury verdicts regarding obviousness, such as that employed in the present case, have become commonplace, if not standard practice. Yet, such general verdicts on the ultimate legal question of obviousness inadvisably sideline judges from fulfilling their critical responsibility to decide this important legal issue. Such verdicts, which are inherently silent about the underlying facts found by the jury on the *Graham* factors, effectively prevent independent judicial review of the legal question of obviousness.

Compounding this trial level problem, these general verdicts also thwart full appellate review

because appellate judges cannot look inside the "black box" of a jury verdict and instead must assume every fact and inference in favor of the jury to the extent possible. As Chief Judge Michel has put it himself, under Federal Circuit precedent, "a general jury verdict on the legal question of obviousness is essentially immune" from judicial review because judges must assume that the jury found whatever facts and made whatever inferences were required to reach the verdict and then affirm that verdict so long as there is substantial evidence in the record to support those facts. *See McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1358 (Fed. Cir. 2001) (Michel, J., dissenting).

The process of reviewing the factual determinations "implicit within the verdict," as advocated by the Federal Circuit blocks judges from fulfilling their duty to make a legal determination of obviousness even though that is expressly contemplated by this Court's jurisprudence. *See McGinley*, 262 F.3d at 1351 (noting that appellate review of a district court's judgment as a matter of law overturning a jury verdict of nonobviousness involves "re-creating the facts as they may have been found by the jury"). This problem is magnified if, as here, the district judge fails to make explicit factual findings in ruling on a motion for JMOL. *See* Petitioners' Br. App. D at 11 (simply finding "sufficient evidence to justify the jury's verdict" by deferring to the jury's credibility determinations regarding the expert testimony presented at trial). This practical reality is not only in conflict with this Court's most recent instructions regarding the application of § 103, but also with the decisions of other circuit courts prior to the inception of the

Federal Circuit concerning the proper degree of deference accorded to a jury verdict on the issue of obviousness.

In short, the jury's effective dominion over the legal question of obviousness in the real world is at odds with the goal of "uniformity and definiteness" in the application of obviousness law to the public grant of a patent that this Court so emphasized in *Graham*. 383 U.S. at 18. It is also at odds with this Court's statement in *KSR* that the findings and reasoning underlying an obviousness conclusion should be "express" to enable judges to fulfill their important responsibility in this area. 550 U.S. at 418.

This Court should therefore grant the petition for a writ of certiorari to address this issue of considerable national importance.

ARGUMENT

I. THIS COURT SHOULD GRANT THE PETITION TO REVIEW WHETHER JUDGES SHOULD INDEPENDENTLY RESOLVE OBVIOUSNESS ISSUES NOTWITHSTANDING A JURY VERDICT

Allowing juries to render general verdicts on the legal question of obviousness has become routine and has been repeatedly blessed by the Federal Circuit. Since *Connell v. Sears, Roebuck & Co.*, 722 F.2d 1542 (Fed. Cir. 1983), the Federal Circuit has consistently held that it is not reversible error for a district judge to surrender the ultimate legal determination of a patent's validity to a jury as long as it retains some control over the ultimate legal issue by reviewing the jury's verdict on motions for judgment as a matter of law or for a new trial. But, in the now-typical circumstance of a general verdict,

the district judge retains control over the obviousness issue in only an attenuated sense.

The practical reality is that the use of general verdicts not only prevents judges from analyzing the question of obviousness based on actual fact findings but also results in inappropriate deference to the jury's ultimate determination of a legal issue. This result is a natural consequence of the Federal Circuit's caselaw holding that implicit factual findings in support of a general verdict of obviousness (or nonobviousness) are only reviewed for substantial evidence. This Court should grant the petition for certiorari to reaffirm that judges, not juries, bear the ultimate responsibility of ruling on issues of law and must therefore engage in an independent assessment of whether an asserted patent is obvious.

A. Federal Circuit Precedent Encourages Judges to Abdicate their Responsibility to Decide Obviousness Issues

In *Graham*, the Court made clear that "the ultimate question of patent validity is one of law," albeit one that is founded on "several basic factual inquiries." 383 U.S. at 17. In stating the basic obviousness test, the *Graham* Court explained the importance of uniformity and consistency to obviousness decision-making:

> That provision [Section 103] paraphrases language which has often been used in decisions of the courts, and the section is added to the statute for ***uniformity and definiteness***.
>
> ***

> We believe that strict observance of the requirements laid down here will result in that ***uniformity and definiteness*** which Congress called for in the 1952 Act.

Id. at 17-18 (emphasis added).

Recently, in *KSR*, this Court explicitly reaffirmed that "[t]he ultimate judgment of obviousness is a legal determination." *KSR*, 550 U.S. at 427. The Court proceeded to assume that the factual determinations upon which the legal conclusion of obviousness is based should be found by the judge, not jurors:

> Often, it will be necessary for a *court* to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the patent at issue. *To facilitate review, this analysis should be made explicit.*"

Id. at 418 (emphasis added). Not only does this passage suggest that the proper decision-maker is a judge, not a jury, but also that allowing a jury to simply reach a verdict on the ultimate question of

obviousness would be improper and harmful to the health of the appellate processes.[2]

Under Federal Circuit precedent, however, once rendered, a jury verdict on obviousness may not be ignored "as though the jury had never been impaneled, had never been instructed on the issue, had never considered the issue, and had never rendered a verdict based on its conclusion." *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F2d 888, 895 (Fed. Cir. 1984) (further noting that the district judge reviewed "the jury's presumed findings"). Instead, the Federal Circuit encourages judges, as it did here, *see* Petitioners' Br. App. A, to make assumptions about the jury's factual findings and review such hypothetical findings which are "implicit within the verdict" to determine whether they are supported by substantial evidence. *McGinley*, 262 F.3d at 1351. This leads to the perverse result that district judges effectively bend over backwards to give deference to a jury verdict on obviousness rather than conduct an independent assessment of the underlying facts and determination of the legal issue.

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[2] Experience has quickly proven that the legal standards set forth in *KSR* are not readily packaged into digestible jury instructions that can be applied easily by juries. Indeed, even a cursory review of the *KSR* opinion demonstrates that its exposition on obviousness law was written for a judge to interpret and apply, not jurors.

B. Special Verdicts Theoretically Could Facilitate Judicial Review of A Jury's Findings But Are Frequently Cumbersome and Impractical

In the absence of guidance from the Federal Circuit, the process of drafting jury instructions and verdict forms on the issue of obviousness has become a complex battleground. The legal determination of obviousness is a complicated inquiry that depends on many factors. As Petitioners point out, *see* Br. at 18, most textbooks on patent law devote entire chapters totaling hundreds of pages to explaining obviousness. Indeed, an entire volume of Professor Chisum's well-regarded treatise on patents concerns obviousness law. In contrast, even the most thorough jury instructions on obviousness will be inadequate to capture these legal nuances. *See, e.g.*, American Intellectual Property Law Association, *Guide to Model Patent Jury Instructions*, available at http://www.aipla.org/Content/ContentGroups/Publications1/Guide_to_Model_Patent_Jury_Instructions.htm; The National Jury Instruction Project, *Model Patent Jury Instructions*, available at http://www.nationaljuryinstructions.org/documents/NationalPatentJuryInstructions.pdf.

As described in further detail below, it has been suggested that district courts could allow juries to make factual findings on a special verdict or to answer special interrogatories. *See Structural Rubber Prods. v. Park Rubber Co.*, 749 F.2d 707, 718 (Fed. Cir. 1984) (encouraging the use of special verdict questions to aid in the review of jury determinations which are otherwise "a black box in

which patents are thrown and emerge intact or invalid by an unknown and unknowable process"). Indeed, before being appointed to the Federal Circuit herself, Judge Moore argued that the Federal Circuit *should* mandate the use of such forms, observing that "district court judges will likely appreciate the guidance from the Federal Circuit on the form of the verdicts." *See* Hon. Kimberly A. Moore, *Juries, Patent Cases, & a Lack of Transparency*, 39 Hous. L. Rev. 779, 799 (2002).

But this approach has its own challenges and is impractical in many cases. Imagine the fact findings in *Graham*, *KSR*, or any other case in this Court's obviousness jurisprudence being written up and agreed upon by a lay jury such that it provides a solid and thorough factual foundation for the district judge, or an appellate court, to make an obviousness determination. For a patent case involving multiple patents, each with numerous claims, the special verdict forms could easily consist of a laundry list of questions relating to obviousness that could be dozens of pages long.

In one of the rare cases where such verdicts were attempted, these questions (and answers) pertained to the secondary considerations that the jury was asked to consider, which is only *one* of the factual areas mandated in *Graham* as part of the obviousness analysis:

> *Whether or not you found the subject matter of any claim of the '051 patent invalid under § 103 in response to question number 2, state below whether any of the following objective*

factors/secondary considerations regarding the '051 patent are established in the evidence:

Whether there was a long-felt need which the subject matter as a whole of the '051 patent fulfilled at the time the invention was made?

YES X NO

Whether others tried but failed to solve the problems addressed by the subject matter of the '051 patent?

YES NO X

Whether the subject matter as a whole of the '051 patent was praised by experts in the industry?

YES X NO

Whether the subject matter as a whole of the '051 patent was praised by the defendants?

YES X NO

Whether the defendants, in infringing the '051 patent, chose not to use the prior art Goodyear design?

YES X NO

Whether the defendants copied the invention of the '051 patent?

YES NO X

Whether the plaintiff's SAF & DRI crossing achieved commercial success?
YES X NO

If you found commercial success as to the SAF & DRI crossing, was it attributable to the claimed invention in the '051 patent?
YES X NO

Whether the Parko crossing achieved commercial success?
YES X NO

If you found commercial success as to the Parko crossing, was it attributable to the claimed invention in the '051 patent?
YES NO X

See Moore, *supra*, at 789-90 (reproducing questions from the Special Verdict Form used in *Structural Rubber Prods. Co. v. Park Rubber Co.*, Case No. 79-CV-1223) (N.D. Ill.)).

In another attempt to test the use of a special verdict, the district judge asked the jury to make these underlying factual findings *and* the ultimate determination of whether the asserted claims were obvious. The special verdict form included the following questions (and answers):

Question 4. Do you find that the following secondary considerations of non-obviousness existed in this case?

(A "YES" answer is an answer for Asyst, a "NO" answer is an answer for Jenoptik.)

a. Commercial success of the invention.

YES X NO

b. A long felt need for the solution provided by the invention

YES X NO

c. Acceptance by others of the invention in the asserted claims of the '421 patent as shown by praise from others in the field or by licensing of the invention claimed.

YES X NO

Question 5. In light of all the evidence, do you find that Jenoptik proved that it is highly probable that the one of ordinary skill in the art in May of 1987 would have found the asserted claims of the '421 patent obvious in view of Hesser and the prior art?

(A "YES" answer is an answer for Jenoptic, a "NO" answer is an answer for Asyst.)

a.	*Claim 2*	*YES*	*NO X*
b.	*Claim 11*	*YES*	*NO X*
c.	*Claim 12*	*YES*	*NO X*
d.	*Claim 13*	*YES*	*NO X*
e.	*Claim 14*	*YES*	*NO X*

See Asyst Techs., Inc. v. Empak, Inc., Case No. C98-20451 JF, Docket Entry 1056, (N.D. Cal. Jan. 31, 2007).

Not only do these examples demonstrate how challenging special verdict questions on the obviousness issue can be, but even these attempts to drag explicit factual findings out of the proverbial "black box" do not adequately reflect the multidimensional nature of the factual inquiries set forth in *Graham*. For example, the questions of whether a product is commercially successful or whether the commercial success of a product is due to the merits of the claimed invention in many cases are better framed as a matter of degree, not as "yes" or "no" answers, *e.g.*, *how* successful was the product or *to what extent* the commercial success is due to the patented invention. Likewise, for a jury to answer whether there is a "long felt need" for the solution provided by the claimed invention, it must necessarily make silent findings regarding what alternatives were available before the invention, to what degree those alternatives failed to adequately addressed the problem, and how long the need was felt. Moreover, all of these factual inquiries must be viewed through the lens of a person of ordinary skill in the art, but the level of experience of that hypothetical person is often hotly disputed and not easily reduced to a binary "yes" or "no" question on a special verdict form. Yet, asking a jury of laypersons to unanimously answer such questions in essay format using special interrogatories might be even more cumbersome.

While one can certainly envision many circumstances where asking the jury to find specific facts is superior to abandoning the whole obviousness issue to the jury, such as where the only factual dispute is whether or when an article was actually published,[3] *Amici* hereby attest to the challenge it can be in many circumstances. Coupled with the Federal Circuit's governing caselaw, which promotes general verdicts of obviousness as described above, this unfortunate situation helps explain why litigants often acquiesce to general verdicts of obviousness and why this Court should grant certiorari to address this troubling state of affairs.

C. Unless this Court Clearly Instructs Judges to Independently Assess the Issue of Obviousness, General Verdicts Will Continue to Impede Judicial Review

As explained above, general verdicts are now the norm, but they stifle the consistency and uniformity of decision-making that is the hallmark of meaningful appellate review based on expressly found facts. Once rendered, a jury's general verdict on the legal question of obviousness can be difficult to evaluate because the court must *presume* that the jury resolved all the underlying facts in favor of the verdict winner and also must accord them every reasonable inference from the evidence. Moreover, in looking for substantial evidence in the record to

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[3] In a simple example, a jury might be asked a special interrogatory regarding whether an article that is undisputed invalidating if it qualifies as "prior art" in fact was published early enough to be prior art.

support a hypothetical set of facts that would support the jury's verdict, the district court is not always required to conduct a lengthy or thorough analysis and in some circuits this decision is reviewed only under an abuse of discretion standard. As noted by Judge Nies, "[t]he trial court's ruling on a JMOL motion may be no more than 'Denied.'" *See In re Lockwood*, *In re Lockwood*, 50 F.3d 966, 989 (1995) (Nies, C.J., dissenting from order denying rehearing en banc).

The Federal Circuit itself has referred to the "black box" nature of jury verdicts, observing that, when evaluating a jury's implicit factual findings regarding the issue of obviousness, it would be "impossible to determine" which pieces of evidence persuaded the jury. *McGinley*, 262 F.3d at 1356. In *McGinley*, for example, the panel majority concluded that there was sufficient evidence to support the jury's conclusion that the patent was not obvious, although it did not even venture a guess as to what evidence actually convinced the jury, and noted that "so long as the parties are content to give the jury unfettered room to operate on dispositive factual issues within the scope of a general verdict request," the appellate court must respect the verdict reached. *Id.*

In his dissent, however, Judge Michel criticized the "common, if unfortunate, practice of allowing the jury to render a general verdict on the ultimate legal conclusion of obviousness without requiring express findings on the underlying factual issues through a special verdict or special interrogatories under Fed. R. Civ. P. 49." *Id.* at 1358. He argued that such a verdict is "essentially immune" from judicial review.

Id. He presciently expressed concern "that after reading our majority opinion, trial courts and our panels will hereafter consider such general verdicts on obviousness immune from meaningful review and that serious legal errors by juries will thus go uncorrected . . . despite our settled case law that a jury's ultimate conclusion on obviousness is a legal question freely reviewable by judges." *Id.* at 1363.

The time is now ripe for this Court to intervene and provide much-needed guidance on what deference, if any, judges should give to a jury's verdict on the issue of obviousness.

II. This Court Should Resolve the Circuit Split and Provide Much-Needed Guidance Regarding the Proper Role of Juries in Making Obviousness Findings

In the wake of *Graham*, several Circuits grappled with the problem of allocating the decision-making responsibility for obviousness issues between judges and juries. Different Circuits had drastically different views on seeking jury findings regarding obviousness and consequently advocated different approaches to instructing juries. This not only highlights the tensions described above but also provides a separate reason that this Court should grant the petition for certiorari as the Federal Circuit has openly acknowledged that its precedent regarding the proper role of a jury in an obviousness inquiry is in conflict with the law of these other Circuits.[4] Because the Federal Circuit's jurisdiction

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[4] As noted by Petitioners, a split between Federal Circuit law and preexisting regional circuit law has been a factor considered by this Court in granting a petition for certiorari,

is national, there is no more percolation that can be expected.

For example, the Ninth Circuit sitting en banc held that a jury's role in deciding whether a patent is obvious under § 103 was limited to making the underlying factual findings because "the court must determine obviousness as a matter of law." *See, e.g., Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647, 650 (9th Cir. 1982) (en banc). In *Sarkisian*, the court held that such findings of fact are made "preferably by detailed special interrogatories in jury trials, and by detailed findings in nonjury trials." *Id.* at 650. If only the legal question of obviousness is submitted to the jury, *i.e.*, "for its guidance," the verdict is advisory and the judge "retains the duty to decide the question independent of the jury's conclusion." *Id.* The Federal Circuit, however, expressly rejected the *Sarkisian* view "that a jury verdict on nonobviousness is at best advisory" and held that a court reviewing such a verdict should ask whether the jury's "presumed findings" could support its conclusion of nonobviousness. *Perkin-Elmer*, 732 F2d at 895 & n.5; *see also Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1234 (Fed. Cir. 1989 (criticizing the "discredited procedure of advisory verdicts" suggested by *Sarkisian*). *Amici* urge this Court to adopt the Ninth Circuit view that general verdicts on the obviousness question should be treated as advisory.

Likewise, the Seventh Circuit sitting en banc has observed that "obviousness is a question of law and

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most recently in *KSR*. *See* Petition for Writ of Certiorari, *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007) (no. 04-1350), 2005 WL 835463, at *20-21.

that in a patent case, as in any other case tried to a jury, questions of law are for the court and questions of fact are for the jury." *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1341) (7th Cir. 1983) (en banc). In *Roberts*, the Seventh Circuit criticized the district court because it did not treat a general jury verdict on obviousness as advisory and thereby "abdicated its control over the legal issue." 723 F.2d at 1342. The Court explained:

> Allocating between judge and jury of their respective decisional responsibilities may be accomplished by the use of special verdicts or special interrogatories or "*by the court's instructions to the jury before it returns a general verdict.*"

Id. at 1341 (quoting *Panther Pumps & Equip. Co. v. Hydrocraft, Inc.*, 468 F.2d 225 (7th Cir. 1972)) (emphasis in original). If a general verdict is sought, jury instructions must explicitly link factual findings with a particular result. In other words, the court must instruct the jury "that if it finds facts A, B, C, and D, it must render a certain verdict." *Id.* at 1341. In this manner, if the jury renders that verdict, it is implicit that the jury found facts A, B, C, and D in reaching that verdict. *See also id.* at 1347 (Posner, J., dissenting on other grounds) (agreeing that "the ultimate question of obviousness is for the court, not the jury, and that the jury's role is limited to deciding subsidiary fact questions, of the who-did-what-to-whom variety."). Yet, *Amici* can verify from experience that this mix and match "menu" approach is not practical for most cases.

The Fifth Circuit, on the other hand, advocated an approach similar to that now employed by the

Federal Circuit in *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763 (5th Cir. 1980). There, the jury instructions included a lengthy description of the legal standard of obviousness to be applied, including a list of secondary factors the jury could take into consideration, but only sought a general verdict on obviousness. *Id.* at 766-67. On appellate review, the panel majority held that "jury findings on the factual underpinnings were implicit in the general verdict" and reviewed those factual findings for substantial evidence. *Id.* at 767. In his partial dissent, Judge Rubin argued that consideration of the *Graham* factors required "jury verdicts on special interrogatories, as permitted by Fed. R. Civ. P. 49(a);" otherwise, the question of patent validity will "effectively become a question for the jury, not one of law for the judge" with "implicit findings on non-obviousness" that cannot be reviewed unless the standard for judgment notwithstanding the verdict is used. *Id.* at 775 (Rubin, J., dissenting) (internal citation omitted). Afterwards, four judges thought that the case should be reheard en banc "because the issues it presents arise in every jury trial of a patent case." *Control Components, Inc. v. Valtek, Inc.*, 616 F.2d 892, 892 (5th Cir. 1980) (Brown, J., dissenting from order denying rehearing en banc).

Another panel of the Fifth Circuit later revisited this issue in *Baumstimler v. Rankin*, 677 F.2d 1061 (5th Cir. 1982) and agreed with Judge Rubin's reasoning that "a general verdict in a patent case deprives the appellate court of any meaningful review." *Id.* at 1071. The *Baumstimler* panel advocated the use of special interrogatories under Fed. R. Civ. P. 40(a). *Id.* The Eighth Circuit took a

similar approach. *See E.I. du Pont de Nemours & Co. v. Berkley and Co.*, 620 F.2d 1247, 1256 n. 5 (8th Cir.1980).

Finally, the Tenth Circuit had a completely different view, acknowledging that the ultimate issue of patent validity is a question of law, but holding that the statutory conditions of patentability such as novelty or nonobviousness are issues of fact. As such, question of obviousness may be submitted in its entirety to the jury and judicial review on judgment as a matter of law (or on appeal) would be limited to determining whether that verdict was supported by substantial evidence. *See, e.g., Norfin Inc. v. Int'l Bus. Machine Corp.*, 625 F.2d 357 (10th Cir. 1980).

In light of these widely-differing divisions of labor between judge and jury on the issue of obviousness, the Court should take this opportunity to resolve the Circuit split. This is a golden opportunity for the Court to clearly empower district judges to exercise their responsibility to resolve the obviousness issue without deferring to general jury verdicts.

III. Functional Considerations Favor Independent Judicial Review of Obviousness Issues

A. Because Patents Involve Public Rights, Obviousness Should be Adjudicated Independently by Judges

The public nature of the patent grant highlights the importance of the judicial role in resolving obviousness questions. From a historical perspective, a patent's validity was customarily

challenged in courts of equity in 18th century England. *See generally In re Lockwood*, 50 F.3d at 983-87 Nies, C.J., dissenting from order denying rehearing en banc). This is because a patent grant involves public rights rather than private rights: "the issuance of a valid patent is primarily a public concern and involves a 'right that can only be conferred by the government' even though validity often is brought into question in disputes between private parties." *Joy Techs., Inc. v. Manbeck*, 959 F.2d 226, 228 (Fed. Cir. 1992) (citing *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985).[5]

In *Lockwood*, for example, the issue was whether there is a right to jury trial on a counterclaim for declaratory judgment of patent invalidity. In her dissent from the denial of rehearing en banc, before this Court granted certiorari, then Chief Judge Nies emphasized that a patent was a "public right" created by Congress and "[a] constitutional jury right to determine validity of a patent does not attach to this public grant." *In re Lockwood*, 50 F.3d at 983 (Nies, C.J.). As noted above, this Court recognized

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[5] Administrative actions—such as the issuance of a patent by the United States Patent and Trademark Office—are always reviewed by a court, not a jury. See *Cox v. United States*, 332 U.S. 442, 453 (1947) (holding that "[t]he concept of a jury passing independently on an issue previously determined by an administrative body or reviewing the action of an administrative body is contrary to settled federal administrative practice"). Some commentators have claimed that there is empirical proof that juries are reluctant to ignore the imprimatur of the government on an issued patent. *See, e.g.*, Adam B. Jaffe & Josh Lerner, *Innovation and Its Discontents: How Our Broken Patent System Is Endangering Innovation and Progress*, at 125 (Princeton 2004) (arguing that juries have a pro-patentee bias).

the importance of this question and granted certiorari on interlocutory appeal, 515 U.S. 1121, but never had an opportunity to clarify whether patent validity should be decided by a judge or a jury because the private litigants in *Lockwood* mooted the issue.

Because this case presents a similar question and its procedural posture is more in line with the typical patent case, this Court should grant certiorari to address how the public nature of the patent grant may require judges to exercise their authority and fulfill their responsibility to evaluate the legal question of obviousness without deference to a jury's general verdict.

B. From a Functional Perspective, Judges are Better Suited than Juries to Decide the Legal Question of Obviousness

This Court has recognized that "functional considerations also play their part in the choice between judge and jury" as decision-makers. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 388 (1996). In *Markman*, this Court addressed the question of claim construction (interpreting the scope of the patent right) and explicitly recognized that the analysis involved mixed questions of law and fact, but ultimately determined that judges were better equipped than juries to deal with the complicated process of construing terms in a patent. *Id.* at 388-90. The *Markman* Court also stressed the "importance of uniformity in the treatment of a given patent as an independent reason to allocate all issues of construction to the court." *Id* at 390.

For similar reasons, obviousness is an issue more appropriately decided by a judge instead of a jury. Regardless, a jury's general verdict on the question of obviousness, if sought, should be accorded no deference. District judges should be given the authority to fulfill their responsibility to resolve complex questions of obviousness, even though there may be factual underpinnings. Indeed, the line between fact and law in an obviousness determination can be very blurry. Although they have often been called fact-intensive inquiries, the *Graham* Court, for example, referred to the secondary considerations of commercial success, long felt need, and failure of others as "legal inferences or subtests" that "focus attention on economic and motivational rather than technical issues and are, therefore, more susceptible of judicial treatment than are the highly technical facts often present in patent litigation." *See Graham*, 383 U.S. at 35-36.

CONCLUSION

The Federal Circuit precedent which permits the legal question of obviousness to be submitted to a jury for consideration is not only in conflict with cases from this Court and from other circuits, but from a practical perspective results in an often-unworkable framework for instructing juries in the majority of patent cases. Given that reality, and the fact that this case is a good vehicle for resolving these issues, the Court should grant the petition and clarify the proper division of labor between a judge and a jury in determining whether an asserted patent is nonobvious under 35 U.S.C. § 103.

September 16, 2009

Respectfully submitted,

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No. 09-198

IN THE

Supreme Court of the United States

MEDELA AG AND MEDELA, INC.,

Petitioners,

v.

KINETIC CONCEPTS, INC., KCI LICENSING, INC., KCI USA, INC., AND WAKE FOREST UNIVERSITY HEALTH SCIENCES,

Respondents.

On Petition For A Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

BRIEF OF AMICI CURIAE INTEL CORPORATION, SAP AMERICA, INC., AND SHORETEL, INC., IN SUPPORT OF PETITIONERS

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QUESTION PRESENTED

Whether a person accused of patent infringement has a right to independent judicial, as distinct from lay jury, determination of whether an asserted patent claim satisfies the "non-obvious subject matter" condition for patentability.

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BRIEF OF *AMICI CURIAE* INTEL CORPORATION, SAP AMERICA, INC., AND SHORETEL, INC., IN SUPPORT OF PETITIONERS

INTEREST OF AMICI CURIAE[1]

The question presented is whether the practice of submitting to juries the ultimate legal issue of obviousness under 35 U.S.C. § 103, rather than reserving that issue for independent judicial resolution, conflicts with this Court's precedents and Congress's stated policy of ensuring uniformity in the patent laws. *Amici curiae* are innovative, high-technology companies that are leaders in the fields of computer hardware and software, communications, information technology, and Internet technology. Accordingly, *amici* have a significant interest in the correct resolution of this question.

Intel is the world's largest semiconductor manufacturer and is also a leading manufacturer of computer, networking, and communications products. SAP America, Inc. is a leading technology company focused on developing innovative software and computer-based business solutions. ShoreTel, Inc., is a leading provider of Pure IP unified communications systems.

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[1] Pursuant to this Court's Rule 37.3(a), letters of consent from all parties to the filing of this brief have been submitted to the Clerk. Pursuant to this Court's Rule 37.6, *amici* state that this brief was not authored in whole or in part by counsel for any party, and that no person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of this brief.

Though *amici* rely on patent laws to protect their intellectual property, they also recognize that "obvious" patents undermine confidence in our intellectual-property system and promote needless litigation. Because intellectual property represents a significant component of *amici*'s businesses, they have a unique interest in ensuring that patent laws optimally promote innovation while preserving competition by minimizing the grant of invalid patents and ensuring uniform and predictable judicial application of the legal standards governing patentability.

The Federal Circuit's practice of allowing juries to resolve obviousness undermines the goal of uniformity that this Court emphasized in *Graham v. John Deere Co.*, 383 U.S. 1 (1966), which held that obviousness presents a question of law for the court. *Amici* believe that reserving the obviousness question for independent judicial resolution, the approach indicated by this Court's precedents and favored by at least two regional circuits, more efficiently serves the goal of promoting uniformity and predictability in the application of the patent laws and ensuring that "obvious" patents are declared invalid.

SUMMARY OF ARGUMENT

Congress created the Federal Circuit in 1982 with the intention of "increas[ing] doctrinal stability in the field of patent law." S. Rep. No. 97-275, at 5 (1981), *reprinted in* 1982 U.S.C.C.A.N. 11, 15. By creating a single court to hear appeals in cases arising under patent law, Congress sought to achieve stability in a field where it saw "a special need for national uniformity." *Id.* at 4. Since 1982, the Federal Circuit has undoubtedly brought greater uniformity to many aspects of patent law. Nevertheless,

in light of the exceeding importance of the patent system to the national economy, this Court has not hesitated to review and modify Federal Circuit precedents in a manner that promotes uniformity by bringing patent law into greater congruity with other areas of law. *See, e.g.*, *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 132 n.11, 137 (2007); *eBay, Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393–94 (2006). The same considerations justify this Court's review here.

I. In *KSR Int'l Co. v. Teleflex, Inc.*, 550 U.S. 398 (2007), this Court clarified the standard for obviousness under Section 103. The effects of that ruling have been muted in the litigation context, however, because even though this Court has repeatedly declared obviousness to be a question of law, *see id.* at 427; *Graham*, 383 U.S. at 17, the Federal Circuit permits (and effectively encourages) submission of that *legal* question to *juries* for a "yes/no" answer that is then given essentially binding effect by the courts. *Perkin-Elmer Corp. v. Computervision Corp.*, 732 F.2d 888, 894–95 (Fed. Cir. 1984). Such "black-box" obviousness determinations are immunized from both independent resolution by district judges and meaningful appellate review, because the courts must presume that the jury found all facts necessary to support its ultimate obviousness conclusion. *Group One Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1304 (Fed. Cir. 2005); *Perkin-Elmer*, 732 F.2d at 895.

A. This approach is inconsistent with this Court's precedents and undermines the Congressional goal of uniformity in patent law. First, the Federal Circuit's approach departs from this Court's

obviousness jurisprudence by failing to preserve a meaningful decisionmaking role for the courts and nullifying the "legal" character of the obviousness determination. *KSR* held that "[t]o facilitate review, [the obviousness] analysis should be made explicit," 550 U.S. at 418, but the approach followed below replaces "explicit" analysis by judges with hypothesized assumptions about what a lay jury may have found.

B. The Federal Circuit's approach is also inconsistent with the standard this Court has established for mixed law-fact issues where uniformity is important. In such contexts "the Court has been reluctant to give the trier of fact's conclusions presumptive force." *Miller v. Fenton*, 474 U.S. 104, 114 (1985). The Federal Circuit's contrary approach conflicts with this Court's recognition in *eBay* and *MedImmune* that creating specialized doctrines for patent law does not enhance uniformity or certainty in the law.

C. The Federal Circuit's approach also conflicts with decisions of the regional circuits rejecting the "black box" approach to resolution of the ultimate issue of obviousness. That conflict breeds further confusion at the district court level and merits this Court's review.

II. Juries are particularly unlikely to reach consistent or accurate results on the issue of obviousness. Untrained in either science or law, jurors face great confusion in applying complex legal standards to equally complex facts, and the Federal Circuit's hypothetical presumption that the jury found all facts necessary to support its legal conclusion effectively insulates the jury's decision from meaningful

appellate review, allowing obvious patents to remain enforceable and thereby harming innovation. This Court should grant certiorari to promote greater uniformity in the patent laws and ensure compliance with its precedents.

ARGUMENT

I. THE FEDERAL CIRCUIT'S STANDARD DEPARTS FROM THIS COURT'S PRECEDENTS, CREATES A CIRCUIT CONFLICT, AND UNDERMINES PATENT-LAW UNIFORMITY

A. This Court's Jurisprudence Requires Independent Judicial Determinations Of Obviousness

Under the Patent and Copyright Clause of the Constitution, Congress is empowered to "promote the Progress of Science and useful Arts" by according for a limited time to "Inventors" the "exclusive Right" to their "Discoveries." U.S. CONST. art 1, § 8, cl. 8. Because Congress controls the grant of patents, the validity of a patent constitutes a public right. *Patlex Corp. v. Mossinghoff*, 758 F.2d 594, 604 (Fed. Cir. 1985) (a patent is "a right that can only be conferred by the government" and "the grant of a valid patent is primarily a public concern"); *Zoltek Corp. v. United States*, 442 F.3d 1345, 1352 (Fed. Cir. 2006) ("patent rights are a creature of federal law"). As with all public rights, Congress controls how and where the right will be vindicated; "the Seventh Amendment does not entitle the parties to a jury trial" on such issues. *Granfinanciera, S.A. v. Nordberg*, 492 U.S. 33, 42 n.4, 51 (1989); *Murray's Lessee v. Hoboken Land & Improvement Co.*, 59 U.S. (18 How.) 272, 284

(1855). For instance, in *Patlex*, the Federal Circuit upheld the authority of the United States Patent and Trademark Office ("PTO"), an administrative tribunal, to determine patent validity in reexamination proceedings, notwithstanding the absence of a jury. 758 F.2d at 604.

Similarly, though an *overall* right to a jury trial in a patent infringement suit seeking damages may exist, the Constitution does not mandate that every specific issue relating to patent *validity* be tried to a jury. *Ross v. Bernhard*, 396 U.S. 531, 538 (1970) ("The Seventh Amendment question depends on the nature of the issue to be tried rather than the character of the overall action."). In *Ross*, for example, the Court stated that a threshold question (the plaintiff's right to sue) could "first be adjudicated as an equitable issue triable to the court," followed if necessary by a jury trial on the plaintiff's claim for damages. *Id.* at 539. There is no reason why a similar approach could not be followed for the issue of obviousness.

Indeed, certain issues that implicate patent validity or enforceability already are heard exclusively by judges, even when (as with claim construction) the issue may involve "receipt of evidence" and "credibility determinations" and thus "'falls somewhere between a pristine legal standard and a simple historical fact.'" *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 378, 388 (1996) (quoting *Fenton*, 474 at 114); *see Baxter Healthcare Corp. v. Spectramed, Inc.*, 49 F.3d 1575, 1584 (Fed. Cir. 1995) (inequitable conduct). Accordingly, this Court's precedent does not establish any comprehensive Seventh Amendment right to have a jury decide all is-

sues of patent validity, particularly issues that (as here, *see* Pet. App. 17a-19a) fundamentally involve "[t]he construction of terms of art" in written documents—the traditional province of judges. *Markman*, 517 U.S. at 390.[2]

Given the "public right" pedigree of patent validity, there is no constitutional bar to independent judicial (rather than jury) resolution of obviousness. "[I]f Congress may assign the adjudication of a statutory cause of action to a non-Article III tribunal [as occurred in *Patlex*], then the Seventh Amendment poses no independent bar to the adjudication of that action by a nonjury factfinder." *Granfinanciera*, 492 U.S. at 53–54.

In adopting the obviousness requirement in the 1952 Patent Act, Congress placed particular emphasis on the need for uniformity and clarity in the patent laws. H.R. Rep. No. 82-1923, at 7 (1952) ("[Section 103] is added to the statute for uniformity and definiteness.").[3] In order to ensure that Congress's

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[2] This Court has looked to historical practices prior to the Framing to shed light on the scope of the Seventh Amendment jury-trial right. *Markman*, 517 U.S. at 376; *Granfinanciera*, 492 U.S. at 41–42. But whatever light that inquiry might shed on other patent-law issues, it can have no bearing on obviousness, which is a creature of the 1952 Patent Act (and even its doctrinal antecedent—the concept of "invention"—arose only in the mid-19th century, *see Graham*, 383 U.S. at 16).

[3] The Constitution does not demand that issues of patentability be tried to juries, but it does require that patents promote the "useful Arts," and this Court has long recognized that obvious variations on prior art devices fail to satisfy that requirement. *See Hotchkiss v. Greenwood*, 52 U.S. (11 How.)

[Footnote continued on next page]

goal of uniformity was achieved, the *Graham* Court held that the obviousness inquiry was a question of law. *Graham*, 383 U.S. at 17–18.

By defining obviousness as an issue of law, the *Graham* Court clearly envisioned a substantial and meaningful role for federal judges in ensuring that the obviousness requirement is enforced and applied uniformly. First, *Graham* ensures that appellate courts possess plenary review over the obviousness determinations of trial courts, thereby enabling appellate courts to correct any errors of law and to promote uniformity in patent decisions. *Id.* Second, *Graham* strongly implies that the district judge rather than the jury must decide the ultimate issue of obviousness. The *Graham* opinion repeatedly states that the obviousness inquiry is to be applied "by the courts" or the PTO. *See Graham*, 383 U.S. at 18–19 ("[W]e have focused attention on the appropriate standard to be applied *by the courts* . . . . [W]e conclude here that the inquiry that the Patent Office

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[Footnote continued from previous page]
248, 267 (1850) ("[U]nless more ingenuity and skill . . . were required . . . than were possessed by an ordinary mechanic acquainted with the business, there was an absence of that degree of skill and ingenuity which constitute essential elements of every invention."). Indeed, *Graham* discussed at length the Constitutional pedigree of the obviousness inquiry prior to reaching the conclusion that it constituted an issue of law. 383 U.S. at 5–12. Given the centrality of non-obviousness to the constitutional directive of promoting "useful Arts," the *Graham* Court could not have intended to leave the obviousness issue to the caprices of lay jurors, who often understand neither the complex science of the patent nor the intricacies of the legal standard for obviousness.

and the courts must make as to patentability must be beamed with greater intensity on the requirements of § 103 . . . ." (emphases added)). Nowhere does the opinion suggest that it intended to depart from the typical practice of reserving legal issues for the judge.

This Court has never held that obviousness should be decided by juries. Rather, in *KSR* the Court again described a system in which judges, not lay juries, decide the obviousness issue. *See, e.g.*, *KSR*, 550 U.S. at 407 ("If *a court*, or patent examiner, conducts this analysis and concludes the claimed subject matter was obvious, the claim is invalid under § 103." (emphasis added)); *id.* at 418 ("*[A] court* can take account of the inferences and creative steps that a person of ordinary skill in the art would employ." (emphasis added)).

Further, *KSR* articulates objectives for the obviousness inquiry that are ill-served by, and inconsistent with, submission of the ultimate question to a jury. *KSR* asserts that "[t]o facilitate review, [the obviousness] analysis should be made explicit." *Id.* Jury verdicts employed in modern patent trials generally contain the antithesis of "explicit" analysis. As in this case (Pet. 6; Pet. App. 42a), verdict forms typically use simple "yes/no" inquiries asking whether the jury found the claim at issue "obvious," or, even more vaguely, found the patent "valid," in light of the jurors' undisclosed assessment of the prior art. Kimberly A. Moore, *Juries, Patent Cases, & A Lack of Transparency*, 39 Hous. L. Rev. 779, 784–86 (2002). The *KSR* Court's analysis of the obviousness inquiry thus confirms the impropriety of submitting the ultimate issue of obviousness for

binding resolution by the jury, because that approach produces inconsistencies and errors that an appellate court cannot correct in light of the obscurity of the jury's reasoning and the rigid presumption that the jury found all facts necessary to support its legal determination of obviousness.

B. This Court's Precedents Mandate a Meaningful Judicial Role in Deciding and Reviewing Legal Issues Based on Underlying Facts Where Uniformity Is Sought

The obviousness inquiry, of course, is not the only area of law in which courts must apply a legal standard to factual issues where uniformity of application is particularly important. This Court has frequently confronted a similar scenario in considering the constitutional permissibility of certain types of evidence in criminal trials. As with the obviousness inquiry, such questions often couple a legal standard, *e.g.*, whether a confession is "involuntary," with underlying issues of historical fact, *e.g.*, the circumstances surrounding the confession. In such cases, this Court has held that the ultimate determination constitutes a question of law or mixed question of law and fact to be decided by a judge at the trial level and subjected to *de novo* review on appeal. In so holding, the Court has emphasized the necessity of uniformity in the interpretation and enforcement of the law, precisely the same policy that animates the patent-law doctrine of obviousness.

This Court confronted such a "hybrid" law/fact question in *Fenton*. In that case, even though federal courts in habeas corpus proceedings are normally obligated to defer to state court fact-finding, the Court

concluded that the voluntariness of a confession was to be treated as a legal inquiry subject to independent and plenary federal court review. *Id.* at 110-111, 115. The *Fenton* Court explained that where "the relevant legal principle can be given meaning only through its application to the particular circumstances of a case, the Court has been reluctant to give the trier of fact's conclusions presumptive force and, in so doing, strip a federal appellate court of its primary function as an expositor of law." *Id.* at 114.

This Court reached similar conclusions with respect to the questions of whether reasonable suspicion or probable cause existed and whether a defendant was "in custody," each of which this Court treated as a hybrid law/fact issue subject to plenary appellate review. *Ornelas v. United States*, 517 U.S. 690, 691, 696 (1996); *Thompson v. Keohane*, 516 U.S. 99, 112–13 (1995). In mandating independent appellate review, the Court emphasized that the contrary approach—*i.e.*, deference to the factfinder's determination—would produce "varied results" that would be "inconsistent with the idea of a unitary system of law" and with the obligation of "appellate courts . . . to maintain control of, and to clarify, the legal principles." *Ornelas*, 517 U.S. at 697; *see Keohane*, 516 U.S. at 115 (reasoning that "the law declaration aspect of independent review potentially may . . . unify precedent[] and stabilize the law").

The analogies between the obviousness inquiry and the criminal-procedure inquiries addressed in these cases are clear: each involves an underlying

constitutional issue,[4] each features a body of law where uniformity is of preeminent value, and each has been declared either a question of law or a mixed question subject to *de novo* review on appeal. In short, when uniformity in a body of law is an important value and no constitutional jury-trial right is implicated, this Court has provided for initial resolution by trial judges and *de novo* review by appellate judges. *Accord Markman*, 517 U.S. at 390-391 (emphasizing "the importance of uniformity" as "an independent reason to allocate all issues of construction to the court" and observing that "[u]niformity would . . . be ill-served by submitting issues of document construction to juries").

Notwithstanding this pattern in the Court's case law, the Federal Circuit's approach effectively assigns the obviousness determination to the jury, with only limited and highly deferential judicial review. *Perkin-Elmer*, 732 F.2d at 894–95. For reasons explored in more detail in Part II below, lay juries, steeped in neither the technical intricacies of the science underlying most patented inventions nor the complexities of obviousness law, cannot be expected to apply that law in a manner that promotes consistency and produces accurate results.

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[4] Although expressed in the Patent Act, the obviousness requirement has a constitutional dimension as well. *See supra* n.3. As the Court explained in *Graham*, "[i]nnovation, advancement, and things which add to the sum of useful knowledge are inherent requisites in a patent system which by constitutional command must 'promote the Progress of . . . useful Arts.' This is the standard expressed in the Constitution and it may not be ignored." 383 U.S. at 6.

Federal judges, by contrast, possess the expertise necessary to apply the governing legal standard to the facts underlying a typical obviousness inquiry. Yet the Federal Circuit's approach precludes both the trial judge's and the appellate court's role of independent review, because the courts are limited to inquiring whether the jury *could* have found facts (whether or not it actually did so) sufficient to support its obviousness determination. *Hallmark Cards*, 407 F.3d at 1304. Such a procedure frustrates the *Graham* Court's goal of uniformity and conflicts with this Court's recognition in *Miller*, *Ornelas*, and *Keohane* that independent, meaningful, *de novo* appellate review is essential when, as here, there is a particular need for uniformity in application and elucidation of the governing legal standard. Accordingly, review is warranted so that this Court can bring the obviousness inquiry into congruence with the approach followed with mixed law/fact questions where uniformity is important, which are determined independently by judges at the trial level and reviewed *de novo* on appeal.

C. The Federal Circuit's Approach Conflicts With Decisions Of The Regional Circuits

In addition to departing from this Court's jurisprudence, the Federal Circuit's approach of leaving obviousness determinations to juries conflicts with the standards adopted by the Seventh and Ninth Circuits, and apparently the Fifth Circuit as well. This Court has recognized that circuit conflicts between the Federal Circuit and regional circuits are an indicator that certiorari is warranted. *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 60 (1998). Such con-

flicts have heightened relevance in light of *Holmes Group, Inc. v. Vornado Air Circulation Sys., Inc.*, 535 U.S. 826 (2002), which held that the regional circuits retain jurisdiction over cases in which a patent claim is asserted only as a counter-claim, *id.* at 834. Thus, Federal Circuit jurisdiction over patent issues is not exclusive, and district courts within the Seventh, Ninth, and potentially the Fifth Circuits therefore face the unenviable task of applying two separate bodies of law to the obviousness inquiry depending upon whether patent rights are asserted on the face of the well-pleaded complaint or instead as counter-claims.

In *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324 (7th Cir. 1983), the Seventh Circuit, sitting en banc, interpreted *Graham*'s declaration that the obviousness inquiry is a question of law as establishing that it is reversible error to submit the obviousness issue to the jury in a manner analogous to the procedure followed by the district court in this case. The *Roberts* court held that the "trial court abdicated its control over the legal issue" because "ask[ing] the jury to pass upon the ultimate legal question, guided only by general instructions, ... impermissibly allowed the jury to be the final arbiter of the legal issue of patent validity." *Id.* at 1342–43.

The Ninth Circuit, also sitting en banc, reached the same result in *Sarkisian v. Winn-Proof Corp.*, 688 F.2d 647, 651 (9th Cir. 1982), holding that "[t]he court must, in all cases, determine obviousness as a question of law independent of the jury's conclusion. Constitutional standards of patentability must not be evaded by improper fact finding." Thus, the Federal Circuit's standard differs from that of at least

two regional circuits, both of which concluded that courts must assume responsibility for independently deciding the ultimate question of obviousness rather than merely submitting that ultimate issue to the jury for binding resolution subject only to highly deferential review.

As the petition explains (Pet. 14–16), the practice in the Fifth Circuit is somewhat more ambiguous, but in its last consideration of the issue, the Fifth Circuit deemed it improper for a district court to submit the ultimate issue of obviousness to the jury, because "the ultimate legal issue of validity should have been determined by the judge, not the jury." *Baumstimler v. Rankin*, 677 F.2d 1061, 1070 (5th Cir. 1982). The court pointed with approval to a previous opinion reasoning that "'meaningful devotion to *Graham* . . . . require[s] jury verdicts on special interrogatories'" and that courts cannot meaningfully review jury verdicts on patent validity merely by "presum[ing] that disputed matters of fact have been resolved favorably to the prevailing party." *Id.* at 1071 (quoting *Control Components, Inc. v. Valtek, Inc.*, 609 F.2d 763, 775 (5th Cir. 1980) (Rubin, J., concurring in part and dissenting in part)).

Thus, the Federal Circuit procedure clearly conflicts with the approach of two sister circuits and appears to be inconsistent with that of a third. Such a conflict not only casts doubt upon the propriety of the Federal Circuit's holding that *Graham* permits jury resolution of obviousness subject only to deferential judicial review, but also fosters confusion for district court judges in the Fifth, Seventh, and Ninth Circuits, who must apply Federal Circuit law in some patent cases and regional circuit law in others. Ac-

cordingly, this Court should grant certiorari to resolve this conflict among the circuits.

II. THE QUESTION PRESENTED HAS SIGNIFICANT PRACTICAL CONSEQUENCES AND THIS CASE PROVIDES A SOUND VEHICLE FOR ITS RESOLUTION

The Federal Circuit's failure to require an independent judicial (rather than lay jury) determination of obviousness presents an issue of substantial and recurring practical importance. Questions of obviousness arise in the vast majority of the thousands of patent cases filed each year. *See* Josh Harrison, *Do the Evolution: The Effect of KSR v. Teleflex on Biotechnology*, 5 Okla. J. L. & Tech. 42, 59 (2009); Administrative Office of the U.S. Courts, 2008 Annual Report of the Director 145 (2008). Allowing lay juries to render ultimate legal decisions without delineating their underlying factual findings provides patent holders possessing invalid patents with a tactical advantage in bringing an infringement suit, renders patent litigation more costly and uncertain, and prevents meaningful judicial review.

Even after this Court's decision in *KSR*, obviousness continues to be the most frequently litigated patent validity issue. *See* Harrison, *supra*, 5 Okla. J. L. & Tech. at 59; J.R. Allison and M.A. Lemley, *Empirical Evidence on the Validity of Litigated Patents*, 26 AIPLA Q.J. 185, 208-09 (1998). Empirical studies also demonstrate that the frequency of jury participation in patent litigation is increasing dramatically. *See* Kimberly A. Moore, *Judges, Juries, and Patent Cases – An Empirical Peak Inside the Black Box*, 11 Fed. Cir. B.J. 209, 210 (2002) (comparing the propor-

tion of patent cases tried to juries in 1940 (2.5%) and in 1999 (59%)).

Empirical evidence also suggests that (1) juries tend to find in favor of patent holders more often than do judges; (2) juries are more likely than judges to find patents valid; and (3) juries tend to favor the party initiating the litigation. *See* Moore, 39 Hous. L. Rev. at 780-81; *see also* Amy Tindell, *Toward a More Reliable Fact-Finder in Patent Litigation*, 13 Marq. Intell. Prop. L. Rev. 309, 323-24 (2009) (discussing reasons parties may prefer jury trials, including to impress juries with PTO's imprimatur of approval, to overwhelm jurors with technical evidence, or to elicit sympathy). Evidence indicates that the outcome of some patent cases depends upon whether a judge or a jury renders the ultimate decision on validity. Moore, 11 Fed. Cir. B.J. at 239-40.

This Court's decision in *KSR*, which rejected the Federal Circuit's rigid teaching-suggestion-motivation ("TSM") test for obviousness, has improved the quality of patents granted by the PTO,[5] but has had no discernible impact on the rate of obviousness determinations by the Federal Circuit,[6] perhaps because that court still appears to require "motivation" in order to establish obviousness. *See, e.g., Eisai Co.*

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5 Arti K. Rai, *Growing Pains in the Administrative State: The Patent Office's Troubled Quest for Managerial Control*, 157 U. Pa. L. Rev. 2051, 2053 (2009).

6 Emer Simic, *The TSM Test is Dead!: Long Live the TSM Test! The Aftermath of KSR, What Was All the Fuss About?*, 37 AIPLA Q.J. 227, 250-51 (2009) (finding that "the rate of obviousness determinations has not increased since *KSR*").

v. Dr. Reddy's Labs., Ltd., 533 F.3d 1353, 1357 (Fed. Cir. 2008) (describing "the requisite motivation"). Thus, while patent prosecution has become more rigorous in light of *KSR*, litigation before juries remains largely unaffected. *See* Carl B. Wischhusen and Jeffrey C. Lee, *Obviousness in the USPTO after KSR v. Teleflex*, 975 PLI/Pat 75 (2009); Esther H. Lim, et al., *Implications of KSR in Prosecution and Litigation: The Standard of Obviousness under 35 U.S.C. § 103*, Managing Intell. Prop., Chinese Ed. (Mar. 2008), *available at* http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=0ffbc063-8857-4dd3-8e91-d2eb2328a7b9. As a result, invalid, obvious patents granted under pre-*KSR* standards may still be upheld by jury verdicts and then subjected only to highly deferential judicial review.

Juries often lack the training and expertise necessary to make correct determinations on the ultimate legal issue of obviousness. Empirical evidence suggests that juries are reluctant to render a patent obvious in direct conflict with an expert PTO examiner's grant of that patent. *See* Moore, 39 Hous. L. Rev. at 787 ("[J]uries are not likely to invalidate patents because juries favor inventors and are unlikely to second-guess the Patent Office that has technically trained examiners who already issued the patents."). Unfortunately, significant numbers of obvious patents were granted under the Federal Circuit's rigid TSM test, making such deference particularly inappropriate. *See* Justin Pats, *Preventing the Issuance of "Bad" Patents: How the PTO Can Supplement Its Practices and Procedures to Assure Quality*, 48 IDEA 409, 411-12 (2008) (citing, as "bad" patents, a patent for a sealed crustless sandwich and one for a method of swinging on a swing).

The lack of an independent judicial determination of obviousness introduces uncertainty, confusion, and potential bias into the resolution of this ultimate legal issue. The consequence is that litigation is less predictable, and obvious patents remain enforceable and valid, in direct contradiction of this Court's teachings in *Graham* and *KSR*.

Anecdotal evidence also indicates that juries experience substantial confusion in rendering decisions on obviousness. Such confusion was apparent in a recent Federal Circuit case in which the jury returned logically irreconcilable verdicts holding a *dependent* claim *invalid* for obviousness while concluding that the *independent* claim (which necessarily encompasses the entirety of the dependent claim) was *valid*. *See Callaway Golf Co. v. Acushnet Co.*, - - - F.3d - - - (Fed. Cir. 2009). While errors of that type are remediable, the seriously confused nature of the jury's findings illustrates the difficulties and lack of understanding that jurors encounter in deciding ultimate questions of obviousness.

Other examples abound of inaccurate jury conclusions regarding obviousness. In the infamous Blackberry case, *NTP, Inc. v. Research in Motion, Ltd.*, 418 F.3d 1282 (Fed. Cir. 2005), the jury found that the patents were valid and infringed. *Id.* at 1291 n.3. After losing its appeal, Research in Motion ("RIM") obtained a license at a cost of $612.5 million. *See* Mark Heinzl, *Blackberry Case Could Spur Patent-Revision Efforts*, Wall St. J., Mar. 6, 2006, at B4. Upon later reexamination of the same patent claims at issue in the litigation, the PTO rejected the claims as invalid. *See* Troy L. Gwartney, *Harmonizing the Exclusionary Rights of Patents With Compulsory Li-*

censing, 50 Wm. & Mary L. Rev. 1395, 1408 (2009). As a result, RIM evidently "purchased the rights to over $650 million of nothing." *Id.* This troubling example demonstrates the harm to innovation caused by inconsistent, confused, opaque, and potentially biased verdicts rendered by juries on the legal question of obviousness.

In 1971, this Court recognized the high costs associated with patent litigation, at a time when the average cost of litigating a patent was $50,000. *Blonder-Tongue Labs., Inc. v. Univ. of Ill. Found.*, 402 U.S. 313, 334-35 (1971). Those costs have skyrocketed in the intervening decades; in 2007, the estimated cost in legal fees to litigate an average patent case was $5.5 million per side. Ian N. Feinberg, et al., *Key Issues in Patent Litigation*, 971 PLI/Pat 235, 276 (2009). At any given time, virtually all major high-technology companies face numerous allegations of patent infringement, which impose massive costs and divert funds and employee resources away from productive activities like research and development. *Patent Litigation: Is it Worth the Expense?*, 26 Genetic Eng'g & Biotech. News (Apr. 1, 2006) *available at* http://www.genengnews.com/articles/chitem_print.aspx?aid=1454&chid=0. Total litigation costs for technology companies are estimated at $4.6 billion per year, a number that has doubled over the past four years. *Hearing on H.R. 1260, the "Patent Reform Act of 2009" Before the House Committee on the Judiciary*, 111th Cong. 11 (2009) (testimony of David Simon, Chief Patent Counsel, Intel Corporation).

Patent holders often utilize the uncertainty associated with jury decision-making to apply undue lev-

erage during licensing or settlement negotiations. Because of the huge direct and indirect costs associated with patent litigation, combined with the substantial risks and uncertainties posed by the prospect of unpredictable jury verdicts, defendants often enter into costly settlements or license agreements involving patents of questionable validity, which ultimately has the effect of increasing costs, decreasing investments in research and development, and raising prices for consumers. *See, e.g., Hearing on "The Patent Reform Act of 2009" Before the Senate Committee on the Judiciary*, 111th Cong. 5 (2009) (testimony of Steven R. Appleton, Chairman and Chief Executive Officer, Micron Technology, Inc.)). Such settlements prevent *KSR* from working to remove invalid patents from the marketplace.

Patent protection for non-obvious inventions serves to encourage innovation, but invalid patents are destructive to our national economy. They hinder competition and retard innovation and technological development, particularly in the area of high technology. Indeed, in the field of information technology, innovation costs arise primarily from licensing fees rather than actual research and development. *See* Andrew Moody, *Patently Obvious: A Dual-Standard Solution to the Diverging Needs of the Information Technology and Pharmaceutical Patent Industries*, 39 Golden Gate U. L. Rev. 71, 88 (2008). Permitting invalid patents to permeate the patent system harms the public by forcing it to "pay tribute to would-be monopolists without need or justification." *See Lear, Inc. v. Adkins*, 395 U.S. 653, 670 (1969).

Against this backdrop, the need for rigorous, independent judicial application and enforcement of the legal standard for obviousness is readily apparent. Unfortunately, however, the Federal Circuit's standard for review of jury verdicts on obviousness falls short of fulfilling that need. Despite the evidence suggesting that juries struggle (at best) with obviousness determinations, judge and jury decisions are affirmed by the Federal Circuit at equal rates. *See* Moore, 39 Hous. L. Rev. at 781; *see also* Amy Tindell, 13 Marq. Intell. Prop. L. Rev. at 323-24. As noted above, the *KSR* decision has not had a noticeable effect on the rate of obviousness determinations by the Federal Circuit. That court's deferential review of jury verdicts, combined with the demonstrated tendency of juries to favor patent-holder plaintiffs on obviousness questions, helps explain that phenomenon, but this simply highlights the problems created by the failure to require independent judicial review of obviousness questions, an approach that does not "facilitat[e] review, uniformity, and possibly post-verdict judgments as a matter of law." *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 39 n.8 (1997).

This case presents a sound vehicle for this Court to address these vital issues. Certiorari is particularly appropriate here because the Federal Circuit, bound by its own precedent, may view itself as unable to initiate appropriate procedural changes in the wake of *KSR*. The Seventh Circuit, in directing the use of special interrogatories to address the "issues of fact subsidiary to the legal question of obviousness" so as to reserve the ultimate question for meaningful judicial resolution, indicated that it was exercising its "supervisory powers." *See Dual Mfg. & Eng'g,*

Inc. v. Burris Indus., Inc., 619 F.2d 660, 667 (7th Cir. 1980) (*en banc*). Early in its history, however, the Federal Circuit disavowed any supervisory authority over the Nation's district courts with regard to matters particular to patent law. *See Petersen Mfg. Co. v. Cent. Purchasing, Inc.*, 740 F.2d 1541, 1552 (Fed. Cir. 1984); *In re Mark Indus.*, 751 F.2d 1219, 1222 (Fed. Cir. 1984); *In re Int'l Med. Prosthetics Research Assocs., Inc.*, 739 F.2d 618, 619 (Fed. Cir. 1984) ("[T]his court is devoid of [supervisory] authority."). The Federal Circuit may therefore view itself as lacking authority to require district courts to submit factual issues to juries by means of special interrogatories (even assuming such jury resolution is appropriate). Accordingly, this Court is in the best position to consider the full range of potential remedies for the important and recurring problem posed by this case.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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